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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 958

[Docket No. FV-90-162]

Idaho-Eastern Oregon Onions; Expenses and Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: This final rule authorizes expenditures and establishes an assessment rate under Marketing Order No. 958 for the 1990–91 fiscal period. Authorization of this budget will permit the Idaho-Eastern Oregon Onion Committee (committee) to incur expenses that are reasonable and necessary to administer the program. Funds to administer this program are derived from assessments on handlers.

EFFECTIVE DATE: July 1, 1990, through June 30, 1991.

FOR FURTHER INFORMATION CONTACT: Caroline C. Thorpe, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2525–S, Washington, DC 20090–6456, telephone 202–447–2020.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 130 and Order No. 958, both as amended (7 CFR part 958), regulating the handling of onions grown in designated counties of Idaho and Malheur County, Oregon. The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the Act.

This rule has been reviewed by the Department in accordance with Departmental Regulation 1512–1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this final rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 30 handlers of Idaho-Eastern Oregon onions under this marketing order, and 450 onion producers. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.2) as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $3,500,000. The majority of onion producers and handlers may be classified as small entities.

The budget of expenses for the 1990–91 fiscal period was prepared by the Idaho-Eastern Oregon Onion Committee (committee), the agency responsible for local administration of the marketing order, and submitted to the Department of Agriculture for approval. The members of the committee are handlers and producers of Idaho-Eastern Oregon onions. They are familiar with the committee's needs and with the costs of goods and services in their local area and are in a position to formulate an appropriate budget. The budget was formulated and discussed in a public meeting. Thus, all directly affected persons have had an opportunity to participate and provide input.

The assessment rate recommended by the committee was derived by dividing anticipated expenses by expected shipments of Idaho-Eastern Oregon onions. Because that rate will be applied to actual shipments, it must be established at a rate that will provide sufficient income to pay the committee's expenses. A recommended budget and rate of assessment is usually acted upon before the season starts, and expenses are incurred on a continuous basis.

The committee met on April 24, 1990, and unanimously recommended a 1990–91 budget of $833,214.32, $249,866.68 less than the previous year. Major reductions were made in the research, promotion and advertising, export, contingency and reserve, travel, miscellaneous, and capital improvements portions of the budget, and the compliance investigator category was eliminated. These reductions offset increases in various categories, which include the salaries of the manager, assistant manager, and secretaries, as well as office supplies and joint expenses.

The committee also unanimously recommended an assessment rate of $0.11 per hundredweight of onions, $0.02 more than last year. This rate, when applied to anticipated fresh market shipments of 7.2 million hundredweight, would yield $792,000 in assessment income. This, along with $41,214.32 in interest income and from the committee's authorized reserves, would be adequate for budgeted expenses. The projected reserve at the end of the 1990–91 fiscal period is $305,737.85, which would be carried over into the next fiscal period. This amount is within the maximum permitted by the order of one fiscal period's expenses.

While this action will impose some additional costs on handlers, the costs are in the form of uniform assessments on all handlers. Some of the additional costs may be passed on to producers. However, these costs will be offset by the benefits derived from the operation of the marketing order. Therefore, the Administrator of the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

A proposed rule was published in the Federal Register on May 25, 1990 (55 FR 21555). That document contained a proposal to add § 958.234 to authorize expenses and establish an assessment rate for the committee. That rule provided that interested persons could file comments through June 4, 1990. No comments were received.

It is found that the specified expenses are reasonable and likely to be incurred and that such expenses and the specified assessment rate to cover such expenses will tend to effectuate the declared policy of the Act.

This action should be expedited because the committee needs to have sufficient funds to pay its expenses

which are incurred on a continuous basis. The 1990–91 fiscal period begins on July 1, 1990, and the marketing order requires that the rate of assessment apply to all assessable onions handled during the fiscal period. In addition, handlers are aware of this action which was recommended by the committee at a public meeting. Therefore, it is also found that good cause exists for not postponing the effective date of this action until 30 days after publication in the **Federal Register** (5 U.S.C. 553).

List of Subjects in 7 CFR Part 958

Marketing agreements, Onions, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 958 is amended as follows:

PART 958—ONIONS GROWN IN CERTAIN DESIGNATED COUNTIES IN IDAHO, AND MALHEUR COUNTY, OREGON

1. The authority citation for 7 CFR part 958 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

2. Section 958.234 is added to read as follows:

Note: This section prescribes the annual expenses and assessment rate and will not be published in the Code of Federal Regulations.

§ 958.234 Expenses and assessment rate.

Expenses of $833,214.32 by the Idaho-Eastern Oregon Onion Committee are authorized and an assessment rate of $0.11 per hundredweight of onions is established for the fiscal period ending June 30, 1991. Unexpended funds may be carried over as a reserve.

Dated: June 14, 1990.

William J. Doyle,

Associate Deputy Director, Fruit and Vegetable Division.

[FR Doc. 90–14206 Filed 6–19–90; 8:45 am]

BILLING CODE 3410-02-M

Farmers Home Administration

7 CFR Parts 1930, 1940, 1944, 1951 and 1965

Implementation of Sections 207 and 401(a) of the Housing and Urban Development Reform Act of 1989

AGENCY: Farmers Home Administration, USDA.

ACTION: Interim rule with request for comments.

SUMMARY: The Farmers Home Administration (FmHA) amends its regulations to implement recently enacted legislation. The intended outcome is to provide guidance on: provisions for charging a surcharge on occupied units in projects with loans made or insured pursuant to a contract entered into on or after June 16, 1990; and establish registration and reporting requirements of persons paid to influence the making of an FmHA housing loan and/or grant.

DATES: The effective date of this regulation is June 16, 1990. Comments must be submitted on or before August 20, 1990.

ADDRESSES: Submit written comments in duplicate to the Office of the Chief, Directives and Forms Management Branch, Farmers Home Administration, room 6346, South Agriculture Building, 14th and Independence Ave., SW., Washington, DC 20250. All written comments made pursuant to this notice will be available for public inspection during regular work hours at the above address.

FOR FURTHER INFORMATION CONTACT: Regarding section 207, contact Carolyn B. Cooksie, Senior Loan Specialist, Multiple Housing Servicing and Property Management Division, room 5328–S, telephone (202) 382–9728. Regarding section 401(a) contact David J. Villano, Senior Loan Specialist, Multiple Family Housing Processing Division, room 5349–S, telephone (202) 382–1608. The address is: USDA–FmHA, South Agriculture Building, 14th and Independence Ave., SW., Washington, DC 20250.

SUPPLEMENTARY INFORMATION:

Classification

This rulemaking action has been reviewed under USDA procedures established in Departmental Regulation 1512–1, which implements Executive Order 12291 and has been determined to be "nonmajor" since the annual effect on the economy is less than $100 million and there will be no significant increase in cost or prices for consumers, individual industries, Federal, State or local Government agencies, or geographic regions. Furthermore, there will be no adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States enterprises to compete with foreign based enterprises in domestic or import markets.

Discussion of Use of Interim Final Rule

It is the policy of the Department to publish notice of proposed rulemaking with a comment period before rules are issued even though 5 U.S.C. 553 exempts rules relating to public property, loans, grants, benefits, or contracts. However, exemptions are permitted where an Agency finds, for good cause, that compliance would be impracticable, unnecessary or contrary to the public interest. This rulemaking package is issued to implement portions of Public Law 101–235, dated December 15, 1989, which required implementation within 180 days of enactment. Because of this short timeframe, this rulemaking document is issued as an interim final rule. Since these changes are legislatively mandated within a short time frame, it would not be possible to publish the regulation as a proposed rule with a 60-day comment period and then publish a final rule with a 30-day implementation period, as required in section 534 of the Housing Act of 1949, as amended. Comments will be accepted for a 60-day period after publication of this interim rule. FmHA will consider such comments, to the extent statutorily permitted, before issuing a final rule.

Environmental Impact Statement

This document has been reviewed in accordance with 7 CFR part 1940, subpart G, "Environmental Program." It is the determination of FmHA that this action does not constitute a major Federal action significantly affecting the quality of the human environment and, in accordance with the National Environmental Policy Act of 1969, Public Law 91–90, an Environmental Impact Statement is not required.

Programs Affected

These programs/activities are listed in the Catalog of Federal Domestic Assistance under Nos.:

10.405—Farm Labor Housing Loans and Grants
10.410—Low Income Housing Loans
10.411—Rural Housing Site Loans
10.415—Rural Rental Housing Loans
10.417—Very Low Income Housing Repair Loans and Grants
10.420—Rural Self-Help Housing Technical Assistance Grants
10.427—Rural Rental Assistance Payments
10.433—Housing Preservation Grants

Intergovernmental Consultation

For the reasons set forth in the Final Rule related Notice(s) to 7 CFR part 3015, subpart V, 10.410 and 10.417 and are excluded from the scope of Executive Order 12372 which requires Intergovernmental consultation with State and local officials. The remaining programs are subject to intergovernmental consultation with State and local officials.

Regulatory Flexibility Act

In compliance with the Regulatory Flexibility Act (Pub. L. 96–354), the undersigned has determined and certified by signature of this document that this rule will not have a significant economic impact on a substantial number of small entities since this rulemaking action does not involve a new or expanded program, and the reporting/registration requirements are imposed by statute.

General Information

Background and Statutory Authority (Section 207)

The Department of Housing and Urban Development Reform Act of 1989, Public Law 101–235, indicates that section 515(t)(4) of the Housing Act of 1949 is amended to provide for a monthly surcharge on occupied units in projects where a loan is made or insured pursuant to a contract entered into on or after June 16, 1990. Borrowers will make monthly payments from project income to FmHA, who will set aside the funds in a special interest bearing account. This money will be used to pay principal and interest payments to offset any rent increases which may result if the project becomes eligible for a guaranteed equity loan, 20 years from the date the loan was made.

In the initial year the surcharge is effective for the project all tenants will pay $2 per month, per unit, for the surcharge, regardless of their income level. In the 19 subsequent years of operation tenants may be subject to paying an additional $2 per month, per unit annual increase if they pay less than 30 percent of their annual adjusted gross income toward rent and utilities. 20 years from the date of the loan which made the project subject to paying the surcharge, annual increases will stop but the surcharge rate established for the unit at that time will continue for the remaining life of the loan.

Exhibit B is being added to subpart K of part 1951 which provides instructions on collecting occupancy surcharges.

Background and Statutory Authority (Section 401(a))

Section 536(d) is added to the Housing Act of 1949 by section 401(a) of the HUD Reform Act and contains two principal features. The first establishes registration and reporting requirements for persons who are paid or for any consideration attempt to influence the award or allocation of assistance by the Secretary. The second imposes limitations on the fees that may be paid to persons attempting to influence the award or allocation of assistance. Section 536(d) also establishes severe administrative and civil penalties against persons who fail to comply with these features.

Section 536(d) is an addition to the Housing Act of 1949, as amended, and therefore, only deals with awards or allocations of housing assistance. Within the context of published housing regulations, FmHA does not use the terms "award or allocation of assistance." The term "award or allocation of assistance" is also not defined in section 536(d). We believe the intent of the legislation is to have persons paid to influence the making of an FmHA housing loan and/or grant, to register and report to FmHA.

Section 401(a) of the HUD Reform Act deals specifically with FmHA. Section 112 of the HUD Reform Act provides similar provisions for HUD. Section 112 is farther reaching and contains additional accountability requirements. It also contains several definitions and more guidance than provided in section 401(a). Where the statutory intent is similar, FmHA has utilized definitions and other guidance from section 112 to assist FmHA and the public in complying with this Public Law. In addition, FmHA has worked with HUD to ensure that our regulations implementing sections 112 and 401(a) are as consistent as statutorily possible.

The reader should also be aware of the provisions of section 319 of the Department of the Interior and Related Agencies Appropriations Act for Fiscal Year 1990, Public Law 101–121, approved October 23, 1989, and more commonly referred to as the "Byrd Amendment." The Byrd Amendment contains a general prohibition on the use of federally appropriated funds for influencing the award of Federal contracts, loans, grants, cooperative agreements and certain post award actions. It also requires disclosure of certain information on payments from non-appropriated funds that are used to influence the aforementioned Federal actions as well as the insurance and guarantee of loans. The Byrd Amendment applies to all Federal agencies and was implemented by a government-wide common rule published in the **Federal Register** on February 26, 1990, at 55 FR 6736. The Byrd Amendment and section 536(d) contain similar but overlapping requirements. Compliance with one Public Law does not preclude compliance with the other Public Law. Persons influencing the making of an FmHA housing loan and/or grant should be familiar with both Public Laws and ensure compliance with either, or both, as applicable.

Section 536(d) places limits and requirements on the "person" attempting to influence the making of an FmHA housing loan and/or grant. A "person" may include a natural person or an entity. In many instances, a person and an entity are involved in the same "influencing" activity. For example, an association may attempt to influence FmHA through one of its employees. In this case, who must comply with section 536(d)—the association or the employee? FmHA believes that section 536(d) should be implemented in a practical manner; that is, the "person" attempting to influence would be subject to section 536(d). Therefore, in the example mentioned above, the employee would have to register and report to FmHA. This is because the employee is the actual person retained to do the influencing. If FmHA required the association to comply with section 536(d), we would not be aware of who the actual "influencers" are, only the associations. We do not believe this is the intent of section 536(d).

It is important to note that although no requirements are placed upon the applicant for the FmHA housing loan and/or grant, the failure of the person paid to influence a request for assistance could adversely affect an applicant. This could include terminating the processing of an application, recapturing any funds advanced, etc. It is therefore incumbent upon FmHA housing applicants to ensure that any person they engage to influence the award or allocation of FmHA assistance complies with section 536(d).

Section 112 of the HUD Reform Act provides an exception for HUD for "expenditures incurred in complying with conditions, requirements, or procedures imposed by the Secretary in connection with any financial assistance." No such exception is provided in section 536(d), however, FmHA believes this is an oversight and the exception is within the statutory intent of the HUD Reform Act. FmHA has administratively chosen to adopt this exception. For example, if FmHA disagrees with the contents of a market study used to establish the need for a Multi-Family Housing complex, and when advised, the applicant pays for additional market analyses and requests local civic leaders to speak to FmHA about the need for housing, this would not be considered an "attempt to influence." This is because the applicant is merely trying to support his/her loan proposal and is complying with FmHA's request for more information.

Although not a provision of the HUD Reform Act, HUD is proposing an exception for litigation. FmHA, like HUD, believes that as a matter of Agency discretion, the very nature of litigation—whether civil, criminal or administrative requires exemption from the rule. The principles underlying litigation involve a persons right to seek and retain counsel, and the right of counsel to represent his or her client. Application of the registration/reporting requirement would be unnecessarily burdensome. In addition, in litigation, the party is not trying to influence FmHA or HUD, they are trying to convince an unbiased third party to rule in their favor.

Consistent with the litigation exception, FmHA has included an exception for appeals requested in accordance with subpart B of part 1900 of this chapter. This subpart contains the Agency's appeal regulations, and provides the right of an appellant to supply additional information at an appeal hearing. The appellant, and person they may pay to assist them with the appeal, are trying to convince an unbiased Hearing Officer to rule in their favor, not influence the person that made the adverse decision.

HUD is also proposing an exception for pre-litigation activities. In their proposed rule, HUD recognizes the serious implications this may have and specifically requests comments on the pre-litigation exception. FmHA has decided not to include the pre-litigation exception in this rulemaking document. In our continuing efforts to work with HUD to ensure consistency between our rulemaking actions implementing the HUD Reform Act, FmHA will discuss with HUD the comments they receive on this issue. If appropriate, FmHA will consider these comments in developing a proposed rule to implement a pre-litigation exception.

Section 536(d)(1)(B) provides an exception to the limitation on fees provision if "* * * professional services related to a project may be donated in whole or in part to a community housing development organization in the event assistance for a project is not awarded. HUD has a similar exception.

Like HUD, we are concerned over the provision that "services * * * may be donated * * * in part" A donation of $1 could trigger this exception. We do not believe this would be within the spirit or intent of the law. Consistent with HUD, we will require that at least 33⅓ percent of the total value of all professional services be donated before the exception is triggered. This provides a meaningful measure of the extent of professional services that would permit special treatment under the exception.

To implement section 536(d), FmHA has developed subpart S to part 1940, "Accountability Requirements of Persons Paid to Influence the Making of an FmHA Housing Loan and/or Grant." Examples of activities addressed in this regulation are provided in exhibit A to subpart S. Exhibit A is not published in the **Federal Register** since it contains only administrative guidance, however a copy is available in any FmHA office for review.

List of Subjects

7 CFR Part 1930

Accounting, Administative practice and procedure, Grant programs—Housing and community development, Loan programs—Housing and community development, Low and moderate income housing—Rental, Reporting requirements.

7 CFR Part 1940

Accountability, Administrative practice and procedure, Grant programs—Housing and community development, Loan programs—Housing and community development, Low and moderate income housing—Rental, Reporting requirements.

7 CFR Part 1944

Administrative practice and procedure, Aged, Farm labor housing, Grant programs—Housing and community development, Handicapped, Home improvement, Loan programs—Housing and community development, Low and moderate income housing—Rental, Migrant labor, Mobile homes, Mortgages, Nonprofit organizations, Public housing, Rent subsidies, Rural housing, Subsidies.

7 CFR Part 1951

Account Servicing, Grant programs—Housing and community development, Loan programs—Housing and community development, Reporting requirements, Rural areas.

7 CFR Part 1965

Administrative practice and procedure, Low and moderate income housing—Rental, Mortgages.

Therefore, chapter XVIII, title 7, Code of Federal Regulations is amended as follows:

PART 1930—GENERAL

1. The authority citation for part 1930 continues to read as follows: 42 U.S.C. 1480; 7 CFR 2.23; 7 CFR 2.70.

Authority:

Subpart C—Management and Supervision of Multiple Family Housing Borrowers and Grant Recipients

2. In § 1930.105, paragraph (b)(12) is added to read as follows:

§ 1930.105 Objective of management and supervision.

* * * * *

(b) * * *

(12) Pay any occupancy surcharges as applicable.

3. Exhibit B, paragraph II, is amended by redesignating subparagraphs AA. through OO. as subparagraphs BB. through PP., adding a new subparagraph AA. and revising the first sentence of redesignated subparagraph OO. to read as follows:

Exhibit B to Subpart C—Multiple Housing Management Handbook

* * * * *

II. *Definitions.*

* * * * *

AA. *Occupancy Surcharge.* A monthly surcharge on occupied units in projects where a loan was made or insured pursuant to a contract entered into on or after June 16, 1990. This surcharge will be collected from borrowers by FmHA and set aside to offset any rent increases which may result when the project becomes eligible for a guaranteed equity loan, 20 years from the date of the last loan made on the project.

* * * * *

OO. *Tenant Contribution.* The portion of approved shelter cost, including occupancy surcharge, paid by the tenant household (tenant rent). * * *

* * * * *

Exhibit B—[Amended]

4. Paragraph V.A.6. is amended by changing the period at the end of the text to a comma and adding the words "including occupancy surcharge, if applicable."

Exhibit B—[Amended]

5. Paragraph V.D.1.b. is amended by revising subparagraph (6). to read as follows:

V. *Management Operations.*

* * * * *

D. * * *

1. * * *

b. * * *

(6) Review of tenant certifications and submission of monthly RA requests and monies collected for occupancy surcharge. Assure protection of project receipts and make invoice and payment disbursements.

* * * * *

Exhibit B—[Amended]

6. Paragraph V.E.1. is amended in subparagraph a. by adding a sentence to

the end of the subparagraph to read as follows:

V. *Management Operations.*

* * * * *

E. * * *

1. * * *

a. * * * Occupancy Surcharges will be applicable in eligible projects.

* * * * *

Exhibit B—[Amended]

7. In Paragraph V.E.1., subparagraph b. is amended by adding the phrase "plus any applicable occupancy surcharge" at the end of the first sentence.

Exhibit B—[Amended]

8. In Paragraph V.E.1., subparagraph c. is amended by adding the sentence "Occupancy Surcharge will not be applicable." to the end of the paragraph.

Exhibit B—[Amended]

9. In Paragraph V.E.1., subparagraph d. is amended by adding the phrase "and occupancy surcharge is not applicable." to the end of the subparagraph.

Exhibit B—[Amended]

10. In Paragraph V.E.1., subparagraph f. is amended by adding the sentence "Occupancy Surcharge will not be collected for non-revenue producing units." to the end of the subparagraph.

Exhibit B—[Amended]

11. Paragraph VI.B.2.c. is amended by redesignating subparagraphs (3) and (4) as subparagraphs (4) and (5), by adding new subparagraph (3) and revising redesignated subparagraph (5) to read as follows:

VI. *Renting Procedure.*

* * * * *

B. * * *

2. * * *

c. * * *

(3) If occupancy surcharge is applicable, the tenant agrees to pay occupancy surcharge at the higher rate, either of the vacated unit or the newly occupied unit.

* * * * *

(5) The agreements in c.(2), (c).(3) and c.(4) of this paragraph are included in the tenant's lease.

* * * * *

Exhibit B—[Amended]

12. Paragraph VIII.A. is amended by redesignating subparagraphs 3. through 7. as subparagraphs 4. through 8. and adding subparagraph 3. to read as follows:

VIII. *Lease Agreements.*

* * * * *

A. * * *

3. Projects in which occupancy surcharge collection is required by law should contain an appropriate clause permitting possible $2 annual increases in surcharge, effective on the project surcharge anniversary date. These increases will be based on the tenant's income and can be charged prior to the expiration of the lease.

* * * * *

Exhibit B—[Amended]

13. In Paragraph VIII.C., subparagraph 2. is amended by adding the phrase "including occupancy surcharge levied, if any." at the end of the subparagraph.

Exhibit B—[Amended]

14. In Paragraph VIII.C.5., subparagraph d. is amended by adding a second sentence to read "If occupancy surcharge is required, tenant agrees to pay higher surcharge rate of unit vacated or newly occupied unit."

Exhibit B—[Amended]

15. In Paragraph XIII.B.2.a., subparagraph (2) is amended by adding the words "occupancy surcharge monies," in the second sentence between the comma and the word "laundry".

Exhibit B—[Amended]

16. In Paragraph XIII.B.2.a., subparagraph (3) is amended by adding the words "including occupancy surcharge." in the next to last sentence between the comma and the word "real".

Exhibit B—[Amended]

17. In Paragraph XIII.C.1., subparagraph b. is amended by adding the words "occupancy surcharge" in the second sentence between the words "overage" and "and".

18. In Exhibit B–1, paragraph 4. is amended by adding a new subparagraph f. to read as follows:

Exhibit B–1 of Subpart C—Management Plan Requirements for FmHA Multiple Family Housing Projects

* * * * *

4 * * *

f. Is the responsible person aware of FmHA requirements regarding projects subject to occupancy surcharge?

* * * * *

Exhibit E—[Amended]

19. In Exhibit E, paragraph ~~II A 2~~ is amended by adding the words "and occupancy surcharge" between the words "allowance" and "within".

PART 1940—GENERAL

20. The authority citation for part 1940 continues to read as follows:

Authority: 42 U.S.C. 1480; 7 CFR 2.23; 7 CFR 2.70.

21. Subpart S to part 1940 is added to read as follows:

Subpart S—Accountability Requirements of Persons Paid to Influence the Making of an FmHA Housing Loan and/or Grant

Subpart S—Accountability Requirements of Persons Paid to Influence the Making of an FmHA Housing Loan and/or Grant

§ 1940.901 Purpose.

This subpart implements section 401(a) of the Housing and Urban Development Reform Act of 1989 ("HUD Reform Act"), Public Law (P.L.) 101–235, approved December 15, 1989, which adds section 536(d) to the Housing Act of 1949. Section 401(a) imposes registration and reporting requirements on any person engaged for pay or for any consideration for the purpose of attempting to influence the making of a Farmers Home Administration (FmHA) housing loan and/or grant, and limits fees a person may charge for this service. Section 401(a) and this subpart do not apply to other FmHA loan and/or grant programs.

§ 1940.902 Objective.

To ensure compliance with the HUD Reform Act and ensure that persons influencing the making of an FmHA housing loan and/or grant register and report their activities to FmHA, and do not seek fees contingent upon obtaining assistance.

§ 1940.903 Definitions.

As used in this subpart *only.*

Communication. Includes written, oral, electronic or any other means of communication.

Department. United States Department of Agriculture .

Engaged. Retained pursuant to an agreement for "pay or for other consideration." The term includes the employment relationship between a person and its officers or employees.

FmHA. Farmers Home Administration.

FmHA housing loan and/or grant. Any loan: insured; direct or guaranteed, made pursuant to the Housing Act of 1949, as amended. The term includes rental assistance (RA) and interest credits. The term does not include contracts, such as procurement contracts, which are subject to the Federal Acquisition Regulation (FAR).

Indian tribe and tribal organization. Those defined in Section 4 of the Indian Self-Determination and Education Assistance Act (25 U.S.C. 450b). Alaskan Natives are included under the definitions of Indian tribes in that Act.

Influence or attempt to influence. Includes (but is not limited to) any effort to effect any aspect, including (but not limited to) the outcome, of the making of an FmHA housing loan and/or grant. Influence may be actual or constructive.

Officer or employee.

(a) In the case of an individual employed by the Department, the term includes:

(1) An individual who is appointed to a position in the Department under title 5, United States Code, including a position under a temporary appointment;

(2) A special government employee, as defined in section 202, title 18, United States Code; and

(3) An individual who is a member or a Federal Advisory Committee, as defined by the Federal Advisory Committee Act, title 5, United States Code.

(b) In the case of an individual employed by a person, the term includes an individual who is in any way retained, designated, appointed, employed, or receiving compensation of any kind from the person to perform duties of any kind and on any basis, including full-time, part-time, or temporary basis.

Pay or other consideration. Includes (but is not limited to) a payment, distribution, loan, advance, deposit, gift of money, or the provision of anything else of value. The term includes pay or other consideration made by, or on behalf of, a person. Pay or other consideration is considered to have been made when the person makes it available to another person without restriction. Receipt of the pay or other consideration is not necessary—only that same has been offered. Ownership by an individual of a single family home financed under the section 502 program does not constitute pay or other consideration.

Person. An individual (including, but not limited to, a consultant, lobbyist, or lawyer), corporation, association, authority, firm, partnership society, State, local government, or any other organization or group of people. This term excludes an Indian tribe, tribal organization, or any other Indian organization.

Professional services. Includes (but is not limited to) legal, technical and other advice/services needed to support the preapplication/application for an FmHA housing loan and/or grant.

§§ 1940.904–1940.905 [Reserved]

§ 1940.906 Interrelationship of this subpart and Pub. L. 101–121.

Section 319 of Public Law 101–121 contains a general prohibition on the use of federally appropriated funds for influencing the award of Federal contracts, loans, grants, cooperative agreements and certain post award actions. It also requires disclosure of certain information on payments from non-appropriated funds that are used to influence the aforementioned Federal actions as well as the insurance and guarantee of loans. Section 319 of Public Law 101–121 applies to all Federal agencies (and all FmHA programs) and was implemented by a government-wide common rule published on February 26, 1990 at 55 FR 6736. Section 319 of Public Law 101–121 and this subpart contain similar but overlapping requirements. Compliance with one Public Law does not preclude compliance with the other Public Law. Persons influencing the making of an FmHA housing loan and/or grant should be familiar with both Public Laws and ensure compliance with either, or both, as applicable.

§ 1940.907 Who must comply with this subpart.

This subpart applies to any person who is engaged for pay or for any consideration to influence, or that should reasonably have the effect of influencing, the making of an FmHA housing loan and/or grant through direct communication with any officer or employee of the Department. The influencing (or attempt to influence) must be related to a specific request for an FmHA housing loan and/or grant although an application/preapplication need not be on file with FmHA. Influencing (or attempting to influence) policy issues, not related to a specific request for an FmHA housing loan and/or grant, is not subject to this subpart. See exhibit A of this subpart (available in any FmHA office) for specific examples of covered actions. Although FmHA applicants do not have any direct responsibilities under this subpart, they should carefully review §§ 1940.913 and 1940.916 of this subpart.

§ 1940.908 Prohibited practices.

Any person meeting the provisions of § 1940.907 of this subpart, shall not seek or receive any fee that is:

(a) Based upon the amount of the FmHA loan and/or grant or the number of units being developed, or

(b) Contingent upon approval of an FmHA housing loan and/or grant by FmHA, *except* that professional services related to a project may be donated in whole or in part to a community housing development organization in the event the FmHA housing loan and/or grant is not made. For the purposes of this paragraph, "donated * * * in part" means that at least 33⅓ percent of the total value of the professional services must be donated to the community housing development organization before the exception is permitted.

§§ 1940.909–1940.910 [Reserved]

§ 1940.911 Reporting and registration requirements.

Any person meeting the provisions of § 1940.907 of this subpart, must:

(a) *Register.* Prior to any influencing activities, Form FmHA 1940–39, "Declaration of Registrant," must be submitted to FmHA.

(b) *Report quarterly.* Each person registering under paragraph (a) of this section must, between the first and tenth day of each calendar quarter, so long as the person's activities continue, submit Form FmHA 1940–40, "Quarterly Declaration of Registrant," to FmHA. Calendar quarters are January 1, April 1, July 1, and October 1.

(c) *Submit registration/reporting forms.* Forms FmHA 1940–39 and FmHA 1940–40, must be submitted to: Farmers Home Administration, USDA, ATTN: 1940–S Coordinator, 14th Street and Independence Avenue, SW., Washington, DC 20250. Persons registering/reporting to FmHA may also be requested by FmHA field offices to supply documentation that they have complied with this Subpart. If requested, the registrant will provide documentation to an FmHA field office to verify that applicable forms have been submitted to the FmHA National Office in Washington, DC.

(d) *Keep records.* Persons required to register/report under this subpart will maintain records and documentation to support information contained in Forms FmHA 1940–39 and FmHA 1940–40.

§ 1940.912 Exceptions.

The following exceptions apply to the registration and reporting requirements contained in § 1940.911 of this subpart:

(a) *Compliance with FmHA requirements.* Where the conditions, requirements, or procedures are imposed, or are reasonably believed by the person to be imposed by law, regulation or written directive (such as an FmHA Administrative Notice [AN], unnumbered letter, Exhibit, application document, etc.), registration or reporting is not required. This includes a request for information by FmHA to support the making of an FmHA housing loan and/or grant not specifically addressed in the applicable program making regulation.

(b) *Litigation.* Litigation against the Department of FmHA is exempt from registration or reporting requirements. In addition, litigation taken by the Department or FmHA, including (but not limited to) civil actions, criminal proceedings, or administrative proceedings pusurant to statute or regulation is exempt.

(c) *Appeals.* Appellants and their representatives who have filed an appeal pursuant to Subpart B of Part 1900 of this chapter are exempt from registration or reporting requirements.

§ 1940.913 Applicability of this subpart to FmHA housing applicants.

This subpart describes the reporting/registration requirements of persons who are engaged for pay or for any consideration for attempting to influence the making of an FmHA housing loan and/or grant. It also establishes limits on fees a person that influences may receive. Although no such requirements are placed upon the applicant for the FmHA housing loan and/or grant, the failure of the person paid to influence a request for assistance could adversely affect an application. This could include the termination of processing an application, recapturing any funds advanced, etc. It is therefore incumbent upon housing applicants to ensure that any person they engage to influence their application complies with this subpart. Applicants should review § 1940.916 of this subpart for specific administrative remedies and civil penalties which may be imposed upon the influencer and/or applicant.

§§ 1940.914–1940.915 [Reserved].

§ 1940.916 Remedies and penalties.

(a) *Administrative remedies.* If the Administrator receives or obtains information providing a reasonable basis to believe that a violation of this subpart has occurred, the Administrator shall:

(1) If the request for assistance has not been approved, determine whether to return the complete request for assistance to the applicant, or take other appropriate actions; or

(2) If the request for assistance has been approved, determine whether to:

(i) Void or rescind approval, subject to review and determination on the record after the opportunity for a hearing;

(ii) Impose sanctions against the violator, including debarment, subject to review and determination on the record after the opportunity for a hearing;

(iii) Stop disbursement of any remaining loan and/or grant funds;

(iv) Recapture any funds that have been advanced;

(v) Permit the applicant to continue with the processing of the FmHA housing loan and/or grant;

(vi) Take any other actions the Administrator deems appropriate.

(3) The Administrator shall publish in the **Federal Register** each action and determination under this paragraph.

(b) *Civil penalties.* Any person who violates this subpart shall be subject to the imposition of a civil penalty in a civil action brought by the United States in an appropriate district court of the United States. A civil penalty may not exceed:

(1) $100,000 in the case of an individual; or

(2) $1,000,000 in the case of other than an individual.

(c) *Disposition of civil penalties.* Notwithstanding any other provision of the law, all civil monetary penalties collected under this subpart shall be deposited in the Rural Housing Insurance Fund.

(d) *Appeals.* Administrative remedies sought and/or taken pursuant to this subpart against the applicant for the FmHA housing loan and/or grant are subject to subpart B of part 1900 of this chapter. Administrative remedies and civil penalties sought and/or taken against the person paid to influence FmHA pursuant to this subpart are not subject to subpart B of part 1900 of this chapter.

§ 1940.917 Nonexclusiveness of remedies.

This subpart shall not be construed to limit the applicability of any other requirements, sanctions, penalties, or remedies established in any other law. Other requirements, sanctions, penalties, or remedies required by FmHA regulations and/or statutes or laws shall apply independently and in addition to the remedies set forth in this subpart.

§§ 1940.918–1940.949 [Reserved]

§ 1940.950 Office of Management and Budget (OMB) reporting and recordkeeping requirements.

The reporting and recordkeeping requirements contained in this regulation have been approved by OMB and have been assigned OMB control number 0575–0139. Public reporting burden for this collection of information is estimated to vary from five minutes to two hours per response, with an average of 1.67 hours per response including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to: Department of Agriculture, Clearance Officer, OIRM, Room 404–W, Washington, DC 20250; and to the Office of Management and Budget, Paperwork Reduction Project (OMB # 0575–0139), Washington, DC 20503.

PART 1944—HOUSING

22. The authority citation for part 1944 continues to read as follows:

Authority: 42 U.S.C. 1489; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart A—Section 502 Rural Housing Loan Policies, Procedures and Authorizations

23. Section 1944.26 is amended by adding paragraph (k) to read as follows:

§ 1944.26 Application processing.

* * * * *

(k) *Accountability.* Applicants should be made aware of the accountability requirements of persons paid to influence the making of an FmHA housing loan and/or grant as described in subpart S of part 1940 of this chapter.

Subpart D—Farm Labor Housing Loan and Grant Policies, Procedures, and Authorizations

24. Section 1944.170 is amended by adding paragraph (d) to read as follows:

§ 1944.170 Processing preapplications.

* * * * *

(d) *Accountability.* Applicants should be made aware of the accountability requirements of persons paid to influence the making of an FmHA housing loan and/or grant as described in subpart S of part 1940 of this chapter.

Subpart E—Rural Rental Housing Loan Policies, Procedures, and Authorizations

25. Section 1944.215 is amended by adding paragraph (v) to read as follows:

§ 1944.215 Special conditions.

* * * * *

(v) *Accountability.* Applicants should be made aware of the accountability requirements of persons paid to influence the making of an FmHA housing loan and/or grant as described in subpart S of part 1940 of this chapter.

PART 1951—SERVICING AND COLLECTIONS

26. The authority citation for part 1951 continues to read as follows:

Authority: 7 U.S.C. 1989, 42 U.S.C. 1480, 5 U.S.C. 301, 7 CFR 2.70.

Subpart K—Predetermined Amortization Schedule System (PASS) Account Servicing

27. Section 1951.504 is amended by redesignating paragraphs (k) through (u) as paragraphs (l) through (v) and by adding a new paragraph (k) to read as follows:

§ 1951.504 Definitions and statements of policy.

* * * * *

(k) *Occupancy surcharges.* A monthly surcharge on occupied units in projects where the last loan was made or insured pursuant to a contract entered into on or after June 16, 1990. These surcharges will be collected from the tenant by the borrower on the same day and in addition to regular rents. The amounts to be collected will be in accordance with exhibit B of this subpart.

* * * * *

§ 1951.506 [Amended]

28. In § 1951.506, paragraph (a)(3) is amended in the second sentence by adding the words "or occupancy surcharge" between the words "overage" and "due."

29. In § 1951.506, paragraph (a)(5)(iv) is redesignated as paragraph (a)(5)(v) and a new paragraph (a)(5)(iv) is added to read as follows:

§ 1951.506 Processing payments.

(a) * * *

(5) * * *

(iv) Any occupancy surcharge due FmHA as described in exhibit B of this subpart.

* * * * *

30. Section 1951.509 is added to read as follows:

§ 1951.509 Occupancy surcharge payments.

(a) *Authorization to Collect Occupancy Surcharge.* Section 515(t)(4) of the Housing Act of 1949, added by section 207 of the Housing and Urban Development (HUD) Act of 1989, Public Law 101–235 which was enacted December 16, 1989, prescribes provisions for FmHA to collect an additional monthly amount from borrowers on all section 515 loans made or insured pursuant to a contract entered into on or after June 16, 1990.

(1) A contract is entered into when a completed Form FmHA 1944–51, "Multiple-Family Housing Obligation—Fund Analysis," is properly delivered to the borrower on or after June 16, 1990. (That delivery date is the date entered in item 51 on Form FmHA 1944–51).

(2) The term "occupancy surcharge" shall be used hereafter to describe this additional monthly charge.

(b) *Occupancy Surcharge Payments.* These monthly payments shall be made from project income which will be collected from tenants. The amount to be collected in the first year after the loan is made or insured will equal $2 per month, for each occupied unit in the project, and shall increase by $2 per unit annually for the next 19 years, based on the income status of tenants residing in each unit.

(1) These annual increases will cease 20 years from the date of the first surcharge payment due on the account.

(2) Annual increases shall not be required for a unit occupied by a family or individual who is paying more than 30 percent of their annual adjusted gross income in rent and utilities.

(3) Surcharge payments will continue after the annual increase period has expired, but will remain at the levels established at year 20 for the remaining life of the loan.

(4) If a subsequent loan is made, the annual increase period for the project will extend for 20 years from the date of the subsequent loan.

(c) *Increases in tenant contribution due to occupancy surcharges.* Borrowers/managers are responsible for initiating and monitoring all surcharge increases. These increases require no prior review by FmHA. All tenants must be notified of any changes in their surcharge contribution in the following manner:

(1) Newly constructed projects in their first year of operation should inform the tenant of the $2 initial charge when their lease is signed. They should also be apprised at that time of possible $2 annual increases based on their income levels.

(2) Tenants in projects where the increase is due to the annual increase or tenants residing in an existing project where a subsequent loan or a servicing action made the project subject to occupancy surcharge, must notify the tenant at least 30 days before the effective date of the increase. This notification will be in writing, outlining any changes that will occur. All tenants in the project will be sent a notification, regardless of whether their actual surcharge contribution changed or not.

(d) *Occupancy Surcharge Account.* Occupancy surcharge monies collected by FmHA will be deposited in the Rural Housing Insurance fund (RHIF) in such a manner as to accrue interest on the total amount of funds collected. These monies will be made available only for payments of principal and interest on guaranteed equity loans made under the authorization of section 515 of the HUD Reform Act of 1989. Payments from the occupancy surcharge account will only be in amounts necessary to ensure that additional project expense from the incurred guaranteed equity loan does not raise rent payments above prescribed maximum rent levels necessary to operate the project. Any monies not expended in the project from which the payments were made, will be used in other projects to make payments of principal and interest on a guaranteed equity loan.

(e) *Occupancy Surcharge Takeout.* The method for allowing payments on these guaranteed equity loans out of the occupancy surcharge account will be forthcoming at such time as needed and will conform with appropriate legislative requirements in effect at that time.

(f) *Collection of Occupancy Surcharge by FmHA.* The policies and methods for collecting surcharge is set forth in exhibit B of this subpart.

§ 1951.510 [Amended]

31. In § 1951.510, paragraph (c)(3) is amended in the first sentence by inserting a comma (,) following the word "charges," removing the word "and" and inserting the words "and occupancy surcharges" between the words "fees" and "have".

32. In § 1951.510, paragraph (e)(4) through (e)(9) are redesignated as paragraphs (e)(5) through (e)(10) and a new paragraph (e)(4) is added to read as follows:

§ 1951.510 Payment application.

* * * * *

(e) * * *

(4) Occupancy surcharges.

* * * * *

33. Exhibit A of subpart K is added and reserved and Exhibit B of subpart K is added to read as follows:

Exhibit A—[Reserved]

Exhibit B of Subpart K—Occupancy Surcharge Payments

I. *Objectives.*

This Exhibit prescribes the methods for arriving at monthly occupancy surcharge rates for tenants in Farmers Home Administration (FmHA) Rural Rental Housing (RRH) and Rural Cooperative Housing (RCH) Section 515 projects. This Exhibit includes all loans made or insured (when a properly completed Form FmHA 1944–51, "Multiple-Family Housing Obligation-Fund Analysis," is delivered to the borrower) on or after June 16, 1990.

II. *Definitions.*

A. *Occupancy Surcharge.* A monthly surcharge on occupied units in projects where a loan was made or insured pursuant to a contract entered into on or after June 16, 1990. This surcharge will be collected from borrowers by FmHA and set aside to offset any rent increases which may result when the project becomes eligible for a guaranteed equity loan, 20 years from the date of the last loan made on the project.

B. *Initial Tenant.* This term refers to a new or existing tenant who occupies a unit in a project the first year the occupancy surcharge is assessed and collected.

C. *Replacement Tenant.* This term refers to a tenant who replaces a tenant in a unit where an occupancy surcharge is or can be assessed and collected.

D. *Surcharge Anniversary Date.* The effective date of surcharge annual increases and is established from the first loan which made the project subject to payment of occupancy surcharge. The date will be 12 months from the first payment due date of that loan.

III. *Initial Understanding With Borrower.*

All RRH and RCH applicants will be informed at the application stage of the agency's occupancy surcharge requirements and procedures. All borrowers will be advised that all occupancy surcharge changes must comply with this Exhibit.

IV. *Eligible Projects.*

A. Loans made pursuant to a contract entered into prior to June 16, 1990, will not be subject to the occupancy surcharge requirements.

B. Loans made pursuant to a contract entered into on or after June 16, 1990, will be subject to all occupancy surcharge requirements within this Exhibit.

V. *Surcharge Payment Due Dates.*

The first monthly occupancy surcharge payment and all payments thereafter will have the same due dates as amortized loan installment due dates. Surcharges will be based on tenants in residence on the first of the month prior to the payment due date.

VI. *Required Occupancy Surcharge Payment Amounts.*

A. The amount of the surcharge for the initial year of operation (first 12 months of surcharge collection) will be $2 per occupied unit, per month, regardless of the tenants income or occupancy status.

B. This surcharge will increase by $2 per unit each year thereafter. Those units occupied by tenants who pay more than 30 percent of their annual adjusted gross income for rent and utilities are exempt from the annual increase. They will remain exempt from surcharge increases until their rent and utilities no longer exceeds 30 percent of their annual adjusted gross income.

C. Vacant units will not be subject to surcharge payments or any annual increases for the duration of the vacancy.

D. Once a surcharge payment is established for a tenant it will never be reduced.

1. If a tenant's income increases, that tenant may become subject to a higher surcharge at the time of regular surcharge annual increases.

2. If a tenant's income decreases, that tenant may be eligible to continue paying the surcharge at their present rate instead of incurring an annual increase.

3. If a tenant moves from one unit to another within the same project, the surcharge will be the higher rate either of the vacated unit or the newly occupied unit.

E. Replacement tenants will be subject to the surcharge level established for the unit during the occupancy of the previous tenant. (At their initial occupancy they will be charged the same level of surcharge that the previous tenant was paying upon move-out.) However, if the replacement tenant is paying more than 30 percent or annual adjusted gross income for rent and utilities, they will not be subject to annual increases, but will continue to pay the surcharge rate in effect at the time of their initial occupancy.

1. If a replacement tenant's income increases and that tenant begins to pay less than 30 percent of their annual adjusted gross income for rent and utilities, they will become subject to the surcharge annual increase.

2. If the unit the replacement tenant moves into was vacant the previous month, they will pay the same rate of surcharge as the last tenant who occupied the unit.

F. Surcharges for projects in connection with transfers, reamortizations, and loan and project consolidations will be handled in accordance with Subpart B of Part 1965 of this chapter.

VII. *Tenants Receiving Rental Assistance (RA).*

Tenants receiving RA will always be subject to annual surcharge increases because their rent contribution will never exceed 30 percent of their annual adjusted gross income.

Example: Basic Rent in Project $200 per month:

Initial Tenant = Net Tenant Contribution (NTC)—$150

Year One—Tenant Pays $150; plus RA Pays $52 [1] = $202

Year Two—$150; plus $54 [2] = $204

If tenant continues to receive RA, surcharge annual increases will continue to be paid from RA.

VIII. *Tenants Paying Overage.*

Tenants paying overage will always be subject to surcharge annual increases. The amount of overage tenants pay will reduce by the additional surcharge amount.

Example:

Basic Rent for Project/$200 per month

Initial Tenant (NTC)—$210 (with no change in income throughout example)

Year One—Tenant Pays $210 ($200 basic plus $2 surcharge plus $8 overage)

Year Two—Tenant Pays $210 ($200 basic plus $4 surcharge plus $6 overage)

Year Five—Tenant Pays $210 ($200 basic plus $10 surcharge plus $0 overage)

Year Six—Tenant Pays $210 ($200 plus $10 surcharge). Tenant experienced no surcharge annual increase because, at this point, 30 percent of their annual adjusted gross income is now being paid toward rent and utilities

IX. *Annual Increases of Occupancy Surcharge.*

A. The annaul surcharge increases will continue for a period of 19 years from the surcharge anniversary date.

B. Twenty years from the first project occupancy surcharge payment the annual increases stop.

C. After the annual increase period stops, the surcharge payment will continue for the remaining life of the loan at whatever level the unit has reached at that time.

D. Annual increases will always be charged in $2 increments, even though the increase may cause some tenants to exceed 30 percent of their annual adjusted gross income by $1.

X. *Surcharge Anniversary Date Rent Change.*

A. The anniversary date is the effective date for surcharge changes due to annual increases and will always be one year from the first surcharge payment collected. (Same as first amortized loan installment due date).

Example: Loan Closed—10/12/90; AED Date—11/01/90

1st Amortized Payment Due—12–01–90

1st Surcharge Payment Due—12–01–90

Surcharge Anniversary Date—12/01 for all subsequent years

B. Rent changes due to the regular tenant recertification process and surcharge changes due to anniversary increases will always be handled as separate actions, even though they could be effective on the same date.

C. Changes in tenant income during the year will never change the occupancy surcharge rate for the tenant until the surcharge anniversary date.

D. When there is a regular rent change in a project (change in basic and market rents), the occupancy surcharge rate will still not be changed until the surcharge anniversary date.

E. When a replacement tenant moves into a unit, they will pay the surcharge at the rate established for the unit during the occupancy of the previous tenant until the surcharge

[1] $50 Basic Rent plus $2 Surcharge.

[2] $50 Basic Rent plus $4 Surcharge.

anniversary date. At the anniversary date, the tenant's income will decide if they are subject to paying an annual increase or continue at the rate of their initial occupancy.

Example

Previous tenant's surcharge rate was $6.

Replacement tenant moves into vacant unit 09/01/90.

The initial surcharge rate for the unit will be $6.

The Project Anniversary Date is 11/01/90. Replacement tenant's surcharge will increase by $2 if they are paying less than 30 percent of their annual adjusted income for rent and utilities. If not, the surcharge rate will remain at $6.

F. On the project anniversary date, all current Forms FmHA 1944–8, "Tenant Certification," must be reviewed for any changes occurring during the year that would change the status of the tenant related to a surcharge annual increase. Surcharge anniversary reviews must be accomplished by the borrower/manager in a timely manner. The process requires no prior review by FmHA and should be handled in accordance with the following:

1. Sixty to thirty days prior to the surcharge anniversary date established for the project all current tenant certifications on file must be reviewed.

2. Any tenant who does not have a current, valid tenant certification on file, will automatically be subject to the surcharge annual increase of $2.

3. All tenants in the project will be sent a notification that the review has occurred regardless of whether they experienced an increase in surcharge or not. As mandated by State law, those tenants whose surcharge contribution increased should be notified at least 30 days prior to the effective date of the increase. This notice should also do the following:

a. Make all tenants aware of the review of their tenant certification and of any changes in the amount of RA they receive or overage they pay, as a result of the review.

b. Offer the tenants an opportunity to meet with management to discuss the changes brought about by the review. (The point of discussion should be solely based on information contained on the tenant certification since the occupancy surcharge requirement is mandated by law.)

XI. *Other Occupancy Surcharge Rent Changes.*

Surcharge increases for existing tenants residing in projects that become subject to the surcharge assessment because of a subsequent loan or a servicing action (i.e., project consolidation), should be notified of the rent change in accordance with section X F 2 of this Exhibit.

XII. *Subsequent Loans.*

A. If the project obtaining the subsequent loan was not previously subject to the occupancy surcharge, all rental units in the project will be affected by the surcharge requirements, and be subject to the same requirements as Paragraph VI of this Exhibit. The due date of the initial $2 surcharge will be the first installment due date of the subsequent loan.

B. If the project to which the subsequent loan is made was already paying surcharge payments, annual increases for the project will be extended 20 years from the first amortized installment due date of the subsequent loan.

1. Existing tenants will continue to pay the surcharge at the rate already established.

2. The anniversary date for the project will remain the same as the one already established for the project by the loan which initiated the requirement for the surcharge.

3. If additional units are added with the subsequent loan, initial tenants moving into the new units will be subject to $2 per unit, per month, until the project anniversary date is reached. On the project anniversary date, all tenant certifications for the project will be checked for eligibility for any surcharge annual increases.

C. Equity loans made for the sole purpose of preventing prepayment in accordance with Exhibit E of Subpart B of Part 1965 of this chapter, will not qualify the project for the occupancy surcharge requirement.

XIII. *Surcharge Collection Process.*

A. Project owners/managers will collect the occupancy surcharge amount from tenants at the same time they collect monthly rents.

B. Project owners/managers will collect information from Form FmHA 1944–8, and report the amount of surcharge due FmHA on Form FmHA 1944–29, "Project Worksheet for Interest Credit and Rental Assistance," both as a project total and per unit amounts.

C. Project owners will remit the collected amount to FmHA when they remit their monthly loan payments as a part of that payment. The method of RA "netting" will also apply to occupancy surcharge.

D. If occupancy surcharges are not remitted to FmHA in correct amounts and in the specified timely manner, and the project account becomes delinquent as a result, late fees will be assessed to the account.

E. FmHA will remit the collected amount to the Finance Office in accordance with the prescribed collection process contained in Subpart B of Part 1951 of this chapter.

XIV. *Tracking Responsibilities.*

A. The occupancy surcharge monies collected nationwide by FmHA will be deposited in the Rural Housing Insurance Fund (RHIF) and will accrue interest to the account on the total amount of funds collected.

B. FmHA will track occupancy surcharge balances by project through the use of the Automated Multi-Housing Accounting System (AMAS).

C. FmHA will report to borrowers the amount of surcharge collected per project once a year on Form FmHA 1951–54, "Annual Statement of Account."

PART 1965—REAL PROPERTY

34. The authority citation for part 1965 continues to read as follows:

Authority: 7 U.S.C. 1989; 42 U.S.C. 1480; 5 U.S.C. 301; 7 CFR 2.23; 7 CFR 2.70.

Subpart B—Security Servicing for Multiple Housing Loans

35. In § 1965.65, paragraph (b)(13) is added to read as follows:

§ 1965.65 Transfer of real estate security and assumption of loans.

* * * * *

(b) * * *

(13) When a subsequent loan is made in connection with a transfer, the project will be subject to the occupancy surcharge provisions of Exhibit B to subpart K of part 1951 of this chapter.

36. In § 1965.68, paragraphs (b) (2) (vii), (viii) and (ix) are added to read as follows:

§ 1965.68 Consolidation.

* * * * *

(b) * * *

(2) * * *

(vii) If none of the loans in any of the projects to be consolidated are subject to the occupancy surcharge provisions of Exhibit B to subpart K of part 1951 of this chapter, the project will not be subject to the surcharge as a result of the project consolidation.

(viii) If one of the projects being consolidated is subject to the occupancy surcharge provisions of Exhibit B to subpart K of part 1951 of this chapter and one project is not, the following conditions apply:

(A) The total units in the project after consolidation will be subject to the occupancy surcharge.

(B) The anniversary date established for the project subject to the occupancy surcharge will remain the same for the new consolidated project.

(C) The annual surcharge increase period will expire twenty (20) years from the date of the first project occupancy surcharge payment for the latest loan in the project being consolidated.

(ix) If both projects being consolidated are subject to the occupancy surcharge provisions of Exhibit B to Subpart K Part 1951 of this chapter, but have different anniversary dates and twenty (20) year expiration dates, the following conditions apply:

(A) The anniversary date of the oldest loan in the projects being consolidated will be the anniversary date for the new consolidated project. This may result in the annual increase for some tenants to exceed a twelve-month period.

Example:

Project 01–1 anniversary date of 5/1
Project 02–2 anniversary date of 10/1
Consolidation date of 7–1–91
Project 01–1 tenants surcharge increase 5/1/91
Oldest loan is the 01–1 Project. New anniversary date for consolidated project–5/1

All tenants in consolidated project reviewed for surcharge increase 05/1/92. (Tenants in old project 02-2 not renewed for a 19-month period)

(B) The annual surcharge increase period will expire twenty (20) years from the date of the first project occupancy surcharge payment for the latest loan in the project being consolidated.

37. In § 1965.70, paragraph (b)(3)(viii) is added to read as follows:

§ 1965.70 Reamortization.

* * * * *

(b) * * *

(3) * * *

(viii) When a subsequent loan is made in connection with a reamortization, the project will be subject to the occupancy surcharge provisions of Exhibit B to subpart K of part 1951 of this chapter.

* * * * *

Dated: June 4, 1990

La Verne Ausman,

Administrator, Farmers Home Administration.

[FR Doc. 90-14369 Filed 6-19-90; 8:45 am]

BILLING CODE 3410-07-M

Animal and Plant Health Inspection Service

9 CFR Part 78

[Docket No. 90-083]

Brucellosis in Cattle; State and Area Classifications

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Affirmation of interim rule.

SUMMARY: We are affirming without change an interim rule that amended the brucellosis regulations concerning the interstate movement of cattle by changing the classification of Indiana from Class A to Class Free. We have determined that Indiana meets the standards for Class Free status. This action relieves certain restrictions on the interstate movement of cattle from Indiana.

EFFECTIVE DATE: July 20, 1990.

FOR FURTHER INFORMATION CONTACT: Dr. G. Frye, Chief Staff Veterinarian, Cattle Diseases and Surveillance Staff, VS, APHIS, USDA, Room 731, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301-436-5533.

SUPPLEMENTARY INFORMATION:

Background

In an interim rule effective January 26, 1990, and published in the **Federal Register** on January 31, 1990 (55 FR 3200-3201, Docket 90-012), we amended the regulations in 9 CFR Part 78 that provide a system for classifying States or portions of States according to the rate of brucella infection present, and the general effectiveness of a brucellosis control and eradication program. We removed Indiana from the list of Class A States in § 78.41(b) and added it to the list of Class Free States in § 78.41(a).

Comments on the interim rule were required to be received on or before April 2, 1990. We did not receive any comments. The facts presented in the interim rule still provide a basis for the rule.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than $100 million; will not cause a major increase in costs or prices for consumers, individual industries, Federal, State, or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived its review process required by Executive Order 12291.

Cattle moved interstate are moved for slaughter, for use as breeding stock, or for feeding. Changing the status of Indiana from Class A to Class Free reduces certain testing and other requirements governing the interstate movement of cattle from Indiana. Testing requirements for cattle moved interstate for immediate slaughter or to quarantined feedlots are not affected by this change. Cattle from certified brucellosis free herds moving interstate are not affected by this change.

The groups affected by this action will be herd owners in Indiana, as well as buyers and importers of Indiana cattle.

There are an estimated 38,000 herds of Indiana, 99 percent of which are owned by small entities, which potentially would be affected by this rule. Most of these herds are not certified-free. Certain test-eligible cattle moved interstate from other than certified-free herds must have a negative test under present Class A status regulations. Last year 51,462 test-eligible cattle in Indiana were tested under the applicable regulations. This testing costs approximately $7 per head or $360,234. If this testing is distributed equally among all herds, Class Free status would potentially save less than $10.00 for each herd.

Therefore, we have determined the changing Indiana's brucellosis status will not significantly affect market patterns, and will not have a significant economic impact on the small entities affected by this rule.

Under these circumstances, the Administrator of the Animal and Plant Health Inspection Service has determined that this action will not have a significant economic impact on a substantial number of small entities.

Paperwork Reduction Act

This rule contains no information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (See 7 CFR part 3015, subpart V.)

List of Subjects in 9 CFR Part 78

Animal diseases, Brucellosis, Cattle, Hogs, Quarantine, Transportation.

Accordingly, we are adopting as a final rule, without change, the interim rule amending 9 CFR 78.41(a) and (b) that was published at 55 FR 3200-3201 on January 31, 1990.

Authority. 21 U.S.C. 111-114a-1, 114g, 115, 117, 120, 121, 123-126, 134b, 134f; 7 CFR 2.17, 2.51, and 371.2(d)

Done in Washington, DC, this 13th day of June 1990.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 90-14209 Filed 6-19-90; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF COMMERCE

Bureau of Export Administration

15 CFR Parts 771 and 799

[Docket No. 81139-0145]

Revision to General License G-COCOM

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Final rule.

SUMMARY: General License G–COCOM authorizes exports to COCOM member countries, Finland and Switzerland of commodities at the August 23, 1988 "PRC Green Zone" level, as described in supplement No. 2 to part 771 of the Export Administration Regulations (EAR) (15 CFR part 76 *et seq.*). It also authorizes exports of commodities eligible for General License G–COM or GFW.

This final rule revises General License G–COCOM by removing supplement No. 2 to part 771 and allowing export of commodities that are described in the current Advisory Notes for the People's Republic of China, as contained in the Commodity Control List (15 CFR 799.1, supp. 1).

Some commodities are ineligible for General License G–COCOM because they are controlled for other than national security reasons or because their export requires more than mere notification to COCOM. Such commodities are described in Advisory Notes containing the phrase "(Not Eligible for General License G–COCOM)." The effect of this rule is to expand commodities eligible for export under General License G–COCOM to those contained in the "PRC Green Zone" as currently listed in the Commodity Control List.

EFFECTIVE DATE: June 20, 1990.

FOR FURTHER INFORMATION CONTACT: Patricia Muldonian, Regulations Branch, Office of Technology and Policy Analysis, Bureau of Export Administration, Telephone: (202) 377–2440.

SUPPLEMENTARY INFORMATION:

Background

The Omnibus Trade and Competitiveness Act (OTCA), signed by the President on August 23, 1988, amended section 5(b)(2) of the Export Administration Act of 1979 (EAA) to require Commerce to eliminate the validated licensing requirement for exports of commodities included in the Advisory Notes for the People's Republic of China (the "PRC Green Zone") as of the effective date of the OTCA to COCOM participating countries and countries determined to be COCOM comparable. On December 6, 1988 (53 FR 49202), the Bureau of Export Administration published a proposed rule with request for comments on ways to implement the legislative requirements.

The Department received comments from 14 firms and associations. In general, comments were opposed to the limited scope of the proposed General License G–COCOM.

Most commenters stated that it was the intent of Congress to allow exports of current "PRC Green Zone" commodities, not to restrict commodities to the "PRC Green Zone" as it existed on August 23, 1988. Commenters felt that the proposed General License G–COCOM would cause confusion in implementation.

The Bureau of Export Administration issued a final rule on July 11, 1989 (54 FR 29011). While the final rule adopted some industry comments and suggestions, it retained the proposed General License G–COCOM structure of listing eligible "Green Zone" commodities, as of the date of enactment of the OTCA, in supplement No. 2 to part 771.

However, the Bureau of Export Administration has now decided to expand commodities eligible for export under General License G–COCOM to those contained in the "PRC Green Zone" as currently listed in the Commodity Control List. This change is consistent with the intent of Congress, as expressed in the OTCA Conference Committee Report, that the PRC Green Line as of the date of enactment "is not intended to be a maximum or static threshold."

Rulemaking Requirements

1. This rule is consistent with Executive Orders 12291 and 12661.

2. This rule does not contain a collection of information subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). As a result of this rule, a reduction of paperwork burden on the public is anticipated. Affected OMB controlled actions include 0694–0005, 0694–0007, and 0694–0010.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism asssessment under Executive Order 12612.

4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553), or by any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. Section 13(a) of the Export Administration Act of 1979 (EAA), as amended (50 U.S.C. app. 2412(a)), exempts this rule from all requirements of section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553), including those requiring publication of a notice of proposed rulemaking, an opportunity for public comment, and a delay in effective date. This rule is also exempt from these APA requirements because it involves a foreign and military affairs function of the United States. Because this rule does not impose a new control it is not subject to section 13(b) of the Export Administration Act.

List of Subjects in 15 CFR Parts 771 and 799

Exports, Reporting and recordkeeping requirements.

Accordingly, Parts 771 and 799 of the Export Administration Regulations (15 CFR parts 730–799) are amended as follows:

1. The authority citations for parts 771 and 799 continue to read as follows:

Authority: Pub. L. 96–72, 93 Stat. 503 (50 U.S.C. app. 2401 et seq.), as amended by Pub. L. 97–145 of December 29, 1981, by Pub. L. 99–64 of July 12, 1985 and by Pub. L. 100–418 of August 23, 1988; E.O. 12525 of July 12, 1985 (50 FR 28757, July 16, 1985); Pub. L. 95–223 of December 28, 1977 (50 U.S.C. 1701 et seq.); E.O. 12532 of September 9, 1985 (50 FR 36861, September 10, 1985) as affected by notice of September 4, 1986 (51 FR 31925, September 8, 1986); Pub. L. 99–440 of October 2, 1986 (22 U.S.C. 5001 et seq.); and E.O. 12571 of October 27, 1986 (51 FR 39505, October 29, 1986).

PART 771—[AMENDED]

2. Section 771.24 is amended by revising paragraphs (a) and (c) to read as follows:

§ 771.24 General License G–COCOM: certain shipments to cooperating countries.

(a) *Scope.* A general license designated G–COCOM is established, authorizing exports to COCOM participating countries, Finland and Switzerland, for use or consumption therein, of commodities that the United States may approve for export to controlled countries with only notification to the COCOM governments, as well as commodities within the China "Green Zone".

(b) * * *

(c) *Eligible exports.* The commodities eligible for export under this general license are those also eligible for General License G–COM or GFW, and those described in Advisory Notes indicating likelihood for approval for exports to the People's Republic of China, unless the Advisory Note contains the phrase "Not Eligible for General License G–COCOM". End-use and quantity restrictions in the Advisory Notes may be disregarded in determining whether G–COCOM may be

used. Commodities controlled under § 776.18(a) of this subchapter (nuclear weapons delivery), as specified in the "Reason for Control" paragraphs of the applicable entries identified on the Commodity Control List, are not eligible for export under this general license. Shipments of eligible commodities are subject to the prohibitions contained in § 771.2(c).

* * * * *

Supplement 2 to Part 771

3. Supplement No. 2 to part 771 is removed.

PART 799—[AMENDED]

Supplement 1 to Part 799

4. In Supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 3 (General Industrial Equipment), in ECCN 1355A, is amended by revising (Advisory) Note 2 for the People's Republic of China to read as follows:

1355A Equipment for the manufacture or testing of electronic components and materials; and specially designed components, accessories and "specially designed software" therefor.

* * * * *

(Advisory) Note 2 for the People's Republic of China (Not Eligible for General License G–COCOM) Licenses will receive favorable consideration for export to satisfactory end-users in the People's Republic of China of equipment controlled for export by sub-paragraph (b)(1) or (b)(2) that can produce patterns finer than 3 micrometers but not finer than 2 micrometers.

Supplement No. 1 to § 799.1 [Amended]

5. In Supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronic and Precision Instruments), ECCN 1565A is amended by revising the ECCN heading and by revising the heading and the introductory text to Advisory Note 19 to read as follows:

ECCN 1565A Electronic computers, "related equipment", equipment or systems containing electronic computers; and specially designed components and accessories therefor.

* * * * *

Advisory Note 19 (for the People's Republic of China) (Optical or magnetic disk drives having an unformatted capacity exceeding 5.04 giga bytes or a maximum bit transfer rate exceeding 6 mega bytes/sec. are NOT ELIGIBLE FOR GENERAL LICENSE G–COCOM): Licenses are likely to be approved for export to satisfactory end-users in the People's Republic of China of peripheral equipment and input/output interface or control units therefor as follows:

* * * * *

Supplement No. 1 to § 799.1 [Amended]

6. In Supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), in ECCN 1567A Advisory Note 16 for the People's Republic of China is amended by adding the phrase "(Not Eligible for General License G–COCOM)" at the end of the heading of the Note.

Supplement No. 1 to § 799.1 [Amended]

7. In Supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), in ECCN 1567A Advisory Note 17 for the People's Republic of China is amended by adding the phrase "(Not Eligible for General License G–COCOM)" at the end of the heading of the Note.

Dated: June 14, 1990.

James M. LeMunyon,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 90–14179 Filed 6–19–90; 8:45 am]

BILLING CODE 3510–DT–M

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15 CFR Parts 771, 779, 786, 787, and 799

[Docket No. 900646–0146]

Establishment of General License GCT; COCOM Trade

AGENCY: Bureau of Export Administration, Commerce.

ACTION: Interim rule with request for comments.

SUMMARY: The Bureau of Export Administration is amending the Export Administration Regulations (EAR) (15 CFR parts 730–799) to reduce licensing requirements on trade with COCOM countries. This rule creates a new General License designated GCT. General License GCT is designed to allow a significant number of items listed on the Commodity Control List (CCL) (15 CFR 799.1, supplement No. 1), under Export Control Commodity Numbers ending in the code letter "A" ("A" level commodities) to be exported to COCOM participating countries.

Certain special requirements will apply to shipments of these "A" level commodities to COCOM participating countries.

This rule also clarifies the scope of controls administered under § 776.18(a) (missile technology delivery) by correcting certain entries in supplement No. 4 to part 779 and in the "Reason for Control" paragraphs of selected entries on the CCL.

DATES: This rule is effective June 20, 1990. Comments should be received by August 6, 1990.

ADDRESSES: Written comments (six copies) should be sent to: Patricia Muldonian, Office of Technology and Policy Analysis, Bureau of Export Administration, Department of Commerce, P.O. Box 273, Washington, DC 20044.

FOR FURTHER INFORMATION CONTACT: Patricia Muldonian, Regulations Branch, Office of Technology and Policy Analysis, Bureau of Export Administration, telephone: (202) 377–2440.

SUPPLEMENTARY INFORMATION:

Background Information

The Bureau of Export Administration (BXA) is amending the Export Administration Regulations (EAR) by revising the validated license requirements for shipments of multilaterally controlled ("A" level) commodities to COCOM participating countries. These changes are based on a review of multilateral export controls maintained by the U.S. and certain allied countries through the Coordinating Committee on Multilateral Export Controls (COCOM). These changes implement an undertaking of the United States, in conjunction with other COCOM participating countries, to create a harmonized and less burdensome system of controls on exports of certain "A" level commodities to COCOM destinations.

The changes represent a significant reduction in the number of validated licenses that will be required for such exports, and in requirements for import certificates and delivery verifications. This will reduce the paperwork burden on exporters because a much smaller number of license applications will have to be filed for exports to destinations in COCOM member countries. Based upon recent export licensing statistics, BXA estimates approximately 85 percent (in terms of dollar value) of items presently requiring a validated license to be exported to COCOM destinations, will no longer require a validated license.

The commodities eligible for export under General License GCT are all "A" level commodities that are not specifically excluded by the "*Commodities Not Eligible for GCT*" paragraphs located in certain ECCNs. The exclusion paragraphs apply to those commodities that exceed the GFW or G–COCOM eligibility levels. Of the 121 ECCNs controlled for national security purposes, a total of 5 ECCNs are excluded in their entirety from eligibility

for GCT for national security purposes, and 11 entries are partially excluded. In addition, 22 other entries are partially or wholly excluded for foreign policy purposes.

Use of General License GCT for exports of eligible "A" level commodities to COCOM participating countries is subject to the following special requirements:

(1) Importers will be required to provide the exporter, prior to shipment, with a signed statement on their commercial documents in which they undertake to import the controlled goods and not to ship them to non-COCOM countries without prior authorization from the appropriate national authorities;

(2) Prior U.S. authorization will be required to redirect these "A" level commodities enroute to any country of destination other than that of the original importer in a COCOM participating country, unless:

(a) The new ultimate country of destination is also a COCOM participating country; and

(b) The new ultimate consignee (importer) provides the party who orders the re-routing with the statement required by (1) above; and

(3) Consistent with the record retention requirements of § 787.13 of the EAR, all exporters and importers will be required to maintain records of all transactions involving such exports of eligible "A" level commodities. Such records are subject to U.S. Government inspection.

Although most "A" level commodities will be eligible for export to COCOM participating countries under General License GCT, a few commodities will continue to require validated licenses and be subject to the import certificate/delivery verification procedure. Exporters will need to check the *Commodities Not Eligible for GCT* paragraph for the applicable Export Control Commodity Number to determine whether a validated license is required for export to COCOM participating countries. Exports of "B" level commodities are not affected by this rule and will continue to require a validated license and any applicable supporting documentation. Of course, exporters are not precluded from using any other applicable general license, individual validated license, or special license. An importer statement is only required for goods that exceed the GFW or G–COCOM levels.

Unless specifically directed otherwise by the applicant, the Office of Export Licensing (OEL) will continue to process license applications to export eligible commodities under standard licensing procedures; such applications will not be returned without action (RWA'd).

Reexports to and among COCOM participating countries under § 774.2(k) will continue to be permitted without change. Similarly, reexports from COCOM countries to non-COCOM countries will not be affected by General License GCT. Reexporters to non-COCOM countries continue to be responsible for obtaining prior U.S. government reexport authorization, as well as complying with their own countries' export controls. (See EAR part 774.)

General License GCT also will not affect export controls on technical data. Any changes affecting technical data controls will be addressed in a separate rule.

The Bureau of Export Administration had considered addressing the COCOM trade issue by creating a new Country Group R for COCOM participating countries. This approach would have authorized exports of most "A" level commodities to COCOM participating countries under General License G-DEST, subject to an importer certification requirement and certain recordkeeping requirements.

After consultation with the appropriate Technical Advisory Committees, in accordance with section 5(h)(2) of the Export Administration Act of 1979, as amended (EAA), the Country Group R approach was rejected in favor of the current General License GCT approach.

The Bureau of Export Administration will continue to work with other COCOM countries that adopt similar licensing systems for the purposes of providing uniform application between countries of the list of items excluded from GCT, as with the GCT procedures.

Rulemaking Requirements

1. This rule is consistent with Executive Orders 12291 and 12661.

2. This rule affects a collection of information subject to the requirements of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*). A reduction in the validated license requirements will result because of this rule, reducing the paperwork burden on the public. Affected OMB controlled collections include 0694–0005, 0694–0007, 0694–0010, and 0694–0015.

3. This rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under Executive Order 12612.

4. Because a notice of proposed rulemaking and an opportunity for public comment are not required to be given for this rule by section 553 of the Administrative Procedure Act (5 U.S.C. 553), or by any other law, under sections 603(a) and 604(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a) and 604(a)) no initial or final Regulatory Flexibility Analysis has to be or will be prepared.

5. Section 13(a) of the Export Administration Act of 1979 (EAA), as amended (50 U.S.C. app. 2412(a)), exempts this rule from all requirements of section 553 of the Administrative Procedure Act (APA) (5 U.S.C. 553), including those requiring publication of a notice of proposed rulemaking, an opportunity for public comment, and a delay in effective date. This rule is also exempt from these APA requirements because it involves a foreign and military affairs function of the United States. Section 13(b) of the EAA does not require that this rule be issued in proposed form because this rule does not impose a new control. Further, no other law requires that a notice of proposed rulemaking and an opportunity for public comment be given for this rule.

However, because of the importance of the issues raised by these regulations, this rule is issued in interim form and comments will be considered in the development of final regulations. Accordingly, the Department encourages interested persons who wish to comment to do so at the earliest possible time to permit the fullest consideration of their views. The Department specifically requests comments on the reexport provisions of this rule and on the commodities excluded from export under General License GCT.

The period for submission of comments will close August 6, 1990. The Department will consider all comments received before the close of the comment period in developing final regulations. Comments received after the end of the comment period will be considered if possible, but their consideration cannot be assured. The Department will not accept public comments accompained by a request that part or all of the material be treated confidentially because of its business proprietary nature or for any other reason. The Department will return such comments and will not consider them in the development of final regulations. All public comments on these regulations will be a matter of public record and will be available for public inspection and copying. In the interest of accuracy and completeness, the Department requires comments in written form. Oral comments must be followed by written memoranda, which will also be a matter

of public record and will be available for public review and copying. Communications from agencies of the United States Government or foreign governments will not be available for public inspection.

In addition to comments on the effects of this rule, BXA would appreciate any comments that would help quantify the extent of the anticipated reduction in licensing burden.

The public record concerning these regulations will be maintained in the Bureau of Export Administration Freedom of Information Records Inspection Facility, room 4525, Department of Commerce, 14th Street and Pennsylvania Avenue, NW., Washington, DC 20230. Records in this facility, including written public comments and memoranda summarizing the substance of oral communications, may be inspected and copied in accordance with regulations published in part 4 of title 15 of the Code of Federal Regulations. Information about the inspection and copying of records at the facility may be obtained from Margaret Cornejo, Bureau of Export Administration Freedom of Information Officer, at the above address or by calling (202) 377–2593.

List of Subjects

15 CFR Parts 771, 786, and 799

Exports, Reporting and recordkeeping requirements.

15 CFR Part 779

Computer technology, Exports, Reporting and recordkeeping reuqirements, Science and technology.

15 CFR Part 787

Boycotts, Exports, Law enforcement, Penalties, Reporting and recordkeeping, requirements.

Accordingly, Parts 771, 779, 786, 787, and 799 of the Export Administration Regulations (15 CFR parts 730–799) are amended as follows:

1. The authority citations for parts 771, 779, 786, 787, and 799 continue to read as follows:

Authority: Pub. L. 96–72, 93 Stat. 503 (50 U.S.C. app. 2401 *et ¼seq.*), as amended by Pub. L. 97–145 of December 29, 1981, by Pub. L. 99–64 of July 12, 1985 and by Pub. L. 100–418 of August 23, 1988; E.O. 12525 of July 12, 1985 (50 FR 28757, July 16, 1985); Pub. L. 95–223 of December 28, 1977 (50 U.S.C. 1701 *et seq.*); E.O. 12532 of September 9, 1985 (50 FR 36861, September 10, 1985) as affected by notice of September 4, 1986 (51 FR 31925, September 8, 1986); Pub. L. 99–440 of October 2, 1986 (22 U.S.C. 5001 *et seq.*); and E.O. 12571 of October 27, 1986 (51 FR 39505, October 29, 1986).

PART 771—[AMENDED]

2. Part 771 is amended by adding a new § 771.25 to read as follows:

§ 771.25 General License GCT; COCOM Trade.

(a) *Scope.* A general license designated GCT is established, authorizing exports to COCOM participating countries of all "A" level commodities except those specifically excluded by the *"Commodities Not Eligible for GCT"* paragraphs in certain Export Control Commodity Numbers (ECCNs) on the Commodity Control List. Exports may be made under GCT only when intended for use or consumption within the importing country, reexport among and consumption within eligible countries, or reexport in accordance with other provisions of the Export Administration Regulations.

(b) *Eligible countries.* The countries that are eligible to receive exports under this general license are Australia, Belgium, Denmark, France, the Federal Republic of Germany, Greece, Italy, Japan, Luxembourg, the Netherlands, Norway, Portugal, Spain, Turkey and the United Kingdom. (Canada is also a COCOM member, but generally there is no license requirement for shipments to Canada (see § 770.3 of this subchapter).)

(c) *Eligible exports.* The commodities eligible for export under this General License GCT are all "A" level commodities that are *not* specifically excluded by the *"Commodities Not Eligible for GCT"* paragraphs located in certain ECCNs. The exclusion paragraphs apply to those commodities that exceed the GFW or G–COCOM eligibility levels. All shipments under this General License GCT are subject to the prohibitions contained in § 771.2(c).

(d) *Importer statement.* Prior to shipping any eligible "A" level commodity that exceeds GFW or G–COCOM limits under General License GCT, the exporter must obtain the following statement, which may be included on the order or other commercial documents that identify the importer, goods to be exported, the country of destination, and that is designed by the foreign importer.

We will import these COCOM controlled goods and will not ship them outside COCOM participating countries without prior authorization from the appropriate national authorities.

(1) *Single/multiple purchase orders.* The importer's statement may cover more than one purchase order. The exporter may request, from the same importer, a statement that covers a single purchase order or multiple purchase orders that may be issued within the next 12 months.

(2) *Transmission of statement.* Either the signed original or a facsimile of the signed original must be received by the exporter before shipment under General License GCT.

(3) *Availability of statement.* The exporter is required to keep the importer statement on file and available for inspection in accordance with the provisions of § 787.13(c) of this subchapter.

(e) *Restrictions on commodities re-directed enroute.* Commodities exported under the provisions of this § 771.25 may not be re-directed enroute to a new country of destruction without prior authorization from the Office of Export Licensing, U.S. Department of Commerce, unless:

(1) The new ultimate country of destination is also a COCOM participating country; and

(2) The new ultimate consignee (importer) provides the re-routing party with a signed importer's statement, as required by § 771.25(d).

(f) *Export Clearance—(1) Shipper's Export Declaration.* A shipment that contains commodities eligible under General Licenses GFW, G-COCOM, and GCT may be included under GCT on the same Shipper's Export Declaration (SED). When making such a shipment, the exporter must place the general license symbol "GCT" in the appropriate space on the SED. Even though the general license symbol "GCT" is noted on the SED, an importer statement is required only for those items on the SED that exceed the GFW or G-COCOM limits (see § 771.25(d)).

(2) *Destination Control Statement.* In accordance with § 786.6 of this subchapter, the exporter is required to enter an appropriate Destination Control Statement on all commercial documents (e.g., the bill of lading, the airway bill, and the commercial invoice) covering an export from the United States under General License GCT. In using the destination control statements listed in § 786.6(d) of this subchapter, Statements No. 1 and 2 may be completed to show "COCOM countries" instead of an individual country of destination, and Statement No. 2 may be completed to show distribution or resale in "COCOM countries."

(g) *Recordkeeping requirements.* Records of transactions involving exports under General License GCT must be maintained in accordance with the recordkeeping requirements of § 787.13 of this subchapter.

PART 779—[AMENDED]

4. In supplement No. 4 to part 779, paragraph (4) "Technical data" is amended by revising the entires for ECCN 1529A and ECCN 1568A to read as follows:

Supplement No. 4—Additional Specifications for Certain Technical Data Requiring a Validated License to all Destinations Except Canada

* * * * *

(4) * * *

ECCN 1522A * * *

ECCN 1529A: Commodities described in paragraphs (c) and (d) under the "List of Equipment Controlled by ECCN 1529A" for launch and ground support equipment usable for complete rocket systems and unmanned air vehicle systems described in § 776.18(a) of this subchapter.

* * * * *

ECCN 1565 * * *

ECCN 1568A: Analog-to-digital converters controlled by paragraph (a) and (e) under the "List of Equipment Controlled by ECCN 1568A."

* * * * *

PART 786—[AMENDED]

4a. Section 786.6 is amended by revising paragraph (a)(1)(ii); by amending paragraph (a)(2) to add the reference "GFW," immediately following the reference to "GLR,"; and by revising paragraph (c)(2) to read as follows:

§ 786.6 Destination control statements.

(a) * * *

(1) * * *

(ii) General License GLV, GTF–US, GTE, GLR, GFW, G-COM, G-COCOM, GCT, or G-CEU.

* * * * *

(c) * * *

(2) *General license shipments.* For a shipment under any general license, except General Licenses G-COCOM and GCT, any of the three destination control statements in paragraph (d) of this section may be used. For shipments under General Licenses G-COCOM and GCT, exporters must use Statement No. 1 or 2.

* * * * *

PART 787—[AMENDED]

§ 787.13 [Amended]

5. Section 787.13(c) is amended in the second sentence by adding the reference "771.25," immediately following the reference "771.22,".

PART 799—[AMENDED]

Supplement No. 1 TO § 799.1 [Amended]

6. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 0 (Metal-Working Machinery), ECCN 2018A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

2018A Specialized machinery, equipment, gear, and specially designed parts and accessories therefor, specially designed for the examination, manufacture, testing, and checking of arms, appliances, machines, and implements of war

Controls for ECCN 2018A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Specialized machinery, equipment, and gear for producing rocket systems (including ballistic missile systems, space launch vehicles, and sounding rockets) and unmanned air vehicle systems (including cruise missile systems, target drones, and reconnaissance drones) capable of delivering nuclear weapons (as defined in § 776.18(a)), their propulsion systems and components, and pyrolytic deposition and densification equipment.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

7. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity group 0 (Metal-Working Machinery), ECCN 1091A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1091A Numerical control units, numerically controlled machine tools, dimensional inspection machines, direct numerical control systems, specially designed sub-assemblies, and specially designed "software". (See § 776.11 for special information to include on the validated license application and reexport request.)

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Machine tools and dimensional inspection machines not excepted from control by paragraphs (b)(i), (b)(iii), and (b)(iv).

* * * * *

Supplement No. 1 TO § 799.1 [Amended]

8. Supplement No. 1 to § 799.1 (the Commodity Control List), in entries listed below, add a new paragraph "*Commodities Not Eligible for GCT:* Entire entry." Immediately following the *GLV $ Value Limit* paragraph of each of the following entries:

A. In Commodity Group 0, Metal-Working Machinery: ECCN 1093A;

B. In Commodity Group 3, General Industrial Equipment: ECCNs 1302A, 3336A, 1357A, 1362A, 1385A, and 1388A;

C. In Commodity Group 4, Transportation Equipment: ECCNs 1418A and 1485A;

D. In Commodity Group 5, Electronics and Precision Instruments: ECCNs 1510A, 1518A, and 1553A and;

E. In Commodity Group 6, Metals, Minerals, and Their Manufactures: ECCNs 3604A and 3609A.

Supplement No. 1 TO § 799.1 [Amended]

9. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 1 (Chemical and Petroleum Equipment), ECCN 2118A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following *GLV $ Value Limit* paragraph to read as follows:

2118A Equipment for the production of military explosives and solid propellants

Controls for ECCN 2118A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Production equipment for the production or rocket propellants.

* * * * *

Supplement No. 1 TO § 799.1 [Amended]

10. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 3 (General Industrial Equipment), ECCN 1355A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1355A Equipment for the manufacture or testing of electronic components and materials; and specially designed components, accessories and "specially designed software" therefore

Controls for ECCN 1355A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Metal-organic chemical vapor deposition reactors; molecular beam epitaxial growth equipment; electron beam systems capable of mask-making or semiconductor device processing; electron beam, ion beam, or X-ray equipment for projection image transfer; and photo-optical or non photo-optical step and repeat or partial field equipment controlled by paragraphs

(b)(1)(iv)(e), (b)(1)(v), (b)(1)(x), (b)(2)(vii), and (b)(2)(viii).

* * * * *

Supplement No. 1 to § 799.1 [Amended]

11. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 3 (General Industrial Equipment), ECCN 1361A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1361A Test facilities and equipment for the design or development of aircraft or gas turbine aero-engines; and specially designed components, and accessories therefor.

* * * * *

Controls for ECCN 1361A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Equipment controlled by paragraph (a), (b), (c), (d), (f), or (g).

* * * * *

Supplement No. 1 to § 799.1 [Amended]

12. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 4 (Transportation Equipment), ECCN 1417A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1417A Submersible systems (including those incorporated in a submersible vehicle) and specially designed components therefor.

* * * * *

Controls for ECCN 1417A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Environmental control systems, navigation systems, and remotely controlled articulated manipulators controlled by paragraphs (a), (b), and (d), respectively.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

13. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 4 (Transportation Equipment), ECCN 1460A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1460A Aircraft and helicopters, including tilt wing and tilt rotor aircraft, aero-engines and aircraft and helicopter equipment.

* * * * *

Controls for ECCN 1460A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Helicoper power transfer systems, gas turbine engines and auxiliary power units, and specially designed components controlled by paragraphs (b), and (c), and (d).

* * * * *

Supplement No. 1 to § 799.1 [Amended]

14. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1501A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1501A Navigation, direction finding, radar and airborne communication equipment.

* * * * *

Controls for ECCN 1501A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Navigation and direction finding equipment and radar equipment controlled under paragraphs (b)(2) through (b)(5) and paragraph (c) usable for launch and ground support equipment, including precision tracking systems usable for complete rocket systems and unmanned air vehicle systems described in § 776.18(a) of this subchapter.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

5. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1516A is amended by revising the heading and by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1516A Receivers, and specially designed components and accessories therefor. (For instruments using time compression of input signal or FFT techniques associated with receivers, see ECCN 1533A)

Controls for ECCN 1516A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Radio receivers, for telemetering and telecontrol equipment, controlled by paragraph (c) and usable for complete rocket systems and unmanned air vehicle systems described in § 776.18(a) of this subchapter and launch and ground support of these systems.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

16. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1517A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1517A Radio transmitters, except radio relay communications equipment (for which see ECCN 1520A), and specially designed components therefor

Controls for ECCN 1517A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Radio transmitters, for telemetering and telecontrol equipment, controlled by paragraph (c) and usable for complete rocket systems and unmanned air vehicle systems described in § 776.18(a) of this subchapter and launch and ground support of these systems.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

17. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1522A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1522A "Lasers" and "equipment containing lasers"

Controls for ECCN 1522A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Equipment containing lasers and measuring systems controlled by paragraphs (b) and (c), as follows: test and alignment equipment for flight control systems usable in the systems described in § 776.18(a) of this subchapter and precision tracking systems usable with the above systems.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

18. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1527A is amended

by adding a *"Commodities Not Eligible for GCT"* paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1527A "Crytographic equipment and specially designed components therefor, designed to ensure secrecy of communications (such as telegraphy, telephony facsimile, video and data communications) or of stored information; and "software" controlling or computers performing the functions of such cryptographic equipment

Controls for ECCN 1527A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Entire entry, *except:*

(1) Automatic bank teller equipment, as defined as devices that provide bank account information, dispense currency, process consumer transactions, or act as point of sale terminals;

(2) Equipment whose only cryptographic function is to authenticate data by calculation of a message authentication code (MAC);

(3) Equipment whose only cryptographic function is to protect passwords or personal identification numbers (PIN) to prevent unauthorized access to computing facilities; and

(4) Television descramblers using analog scrambling techniques for the purpose of entertainment.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

19. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1529A is amended by adding a *"Commodities Not Eligible for GCT"* paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1529A Electronic equipment for testing, measuring or for microprocessor/microcomputer development, as follows

* * * * *

Controls for ECCN 1529A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Equipment controlled under paragraphs (c) and (d) for launch and ground support equipment usable for complete rocket systems and unmanned air vehicle systems described in § 776.18(a) of this subchapter.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

20. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1531A is amended by adding a *"Commodities Not Eligible for GCT"* paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1531A "Frequency synthesizers" (and equipment containing such "frequency synthesizers")

Controls for ECCN 1531A

* * * * *

GLV $ Value Limit * * *

Commodities Not Eligible for GCT: Frequency synthesizers, airborne communication equipment, digitally-controlled radio receivers, and radio transmitters controlled by paragraphs (a) and (c) through (e), that will be used as follows:

(1) As avionics equipment in complete rocket systems and unmanned air vehicle systems described in § 776.18(a);

(2) In vibration test equipment (ECCN 1362A) and wind tunnels (ECCN 1361A); or

(3) In launch and ground support equipment usable for the systems described in § 776.18(a) of this subchapter.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

21. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1533A is amended by revising the heading and by adding a *"Commodities Not Eligible for GCT"* paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1533A Signal analyzers (including spectrum analyzers), with any of the following characteristics, and specially designed components, and accessories therefor

* * * * *

Controls for ECCN 1533A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: "Dynamic signal analyzers" controlled by paragraph (b) for launch and ground support equipment usable for complete rocket systems and unmanned air vehicle systems described in § 776.18(a) of this subchapter.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

22. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1564A is amended by adding a *"Commodities Not Eligible for GCT"* paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1564A "Assemblies" of electronic components, "modules", printed circuit boards with mounted components, "substrates" and integrated circuits, including packages therefor

Controls for ECCN 1564A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Analog-to-digital converters that are not excluded from control under 1564A by paragraph (d)(2)(D)(m)(1) when usable in systems described in § 776.18(a) of this subchapter and having any of the following characteristics: rated for continuous operation at temperatures below −45°C to above 55°C; designed to meet military specifications for ruggedized equipment, or modified for military use; or designed for radiation resistance.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

23. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1565A is amended by removing the parenthetical phrase immediately following the heading and adding a new Note; and by adding a *"Commodities Not Eligible for GCT"* paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1565A Electronic computers, "related equipment", equipment or systems containing electronic computers; and specially designed components and accessories therefor

Note: For "specially designed software", see supp. No. 3 to part 779.

Controls for ECCN 1565A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Electronic computers and related equipment, as follows:

(1) Digital computers and related equipment controlled by paragraph (h) that have a total processing data rate exceeding 2,000 million bits per second.

(2) Analog computers, equipment or systems containing analog computers, and digital computers that contain the design features described in paragraphs (a), (b), (f), and (g).

(3) Analog and hybrid computers, controlled by paragraphs (c) and (d), and (h) as applicable to (d), when combined with specially designed software for modeling, simulation, or design integration of complete rocket

systems and unmanned air vehicle systems described in § 776.18(a) of this subchapter.

(4) Digital computers used as ancillary equipment for test facilities and equipment that are controlled by ECCNs 1361A and 1362A for nuclear weapons delivery non-proliferation purposes.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

24. In supplement No. 1 to §799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1568A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph; and by revising the *Reason for Control* paragraph to read as follows:

1568A Analog-to-digital and digital-to-analog converters, position encoders and transducers, and specially designed components and test equipment therefor.

* * * * *

Controls for ECCN 1568A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Analog-to-digital converters controlled by paragraph (a) or (e).

Processing Code: * * *

Reason for Control: National security; nuclear non-proliferation; foreign policy. Foreign policy controls apply to commodities described in paragraphs (a) and (e) for nuclear weapons delivery purposes.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

25. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1585A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1585A Cameras, components and photographic recording media.

* * * * *

Controls for ECCN 1585A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: High speed photographic equipment controlled by paragraph (b), (c), or (d).

* * * * *

Supplement No. 1 to § 799.1 [Amended]

26. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1587A is amended by revising the heading and by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1587A Quartz crystals and assemblies thereof in any stage of fabrication (i.e., worked, semi-finished or mounted).

Controls for ECCN 1587A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Temperature compensated crystal oscillators controlled by paragraph (c).

* * * * *

Supplement No. 1 to § 799.1 [Amended]

27. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 5 (Electronics and Precision Instruments), ECCN 1595A is amended by adding a "*Commodities Not Eligible for GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1595A Gravity meters (gravimeters), gravity gradiometers and specially designed components therefor, except those items listed in paragraphs (a) and (b) below.

Controls for ECCN 1595A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Gravity meters (gravimeters), gravity gradiometers, and specially designed components, as follows:

(1) Designed or modified for airborne or marine use, *and*;

(2) Having a static or operational accuracy of one milligal or better, with a time to steady state registration of two minutes or less.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

28. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 7 (Chemicals, Metalloids, Petroleum Products and Related Materials), ECCN 1715A is amended by adding a "*Commodities Not Eligible For GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1715A Boron, as described in this entry.

Controls for ECCN 1715A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Propellants and constituents as follows: High energy density fuels, such as Boron Slurry, having an energy density of 40×10^6 joules/kg or greater.

* * * * *

Supplement No. 1 to § 799.1 [Amended]

29. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 7 (Chemicals, Metalloids, Petroleum Products and Related Materials), ECCN 1746A is amended revising the heading and by adding a "*Commodities Not Eligible For GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1746A Non-fluorinated polymeric substances, as follows, and manufactures thereof.

Controls for ECCN 1746A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Propellants and constituents as follows: Polymeric substances, specifically carboxyl terminated polybutadienes (CTPB) and hydroxyl terminated polybutadienes (HTPB) controlled by paragraphs (k)(1) and (k)(2).

* * * * *

Supplement No. 1 to § 799.1 [Amended]

29. In supplement No. 1 to § 799.1 (the Commodity Control List), Commodity Group 7 (Chemicals, Metalloids, Petroleum Products and Related Materials), ECCN 1746A is amended revising the heading and by adding a "*Commodities Not Eligible For GCT*" paragraph immediately following the *GLV $ Value Limit* paragraph to read as follows:

1763A Fibrous and filementary materials that may be used in organic "matrix," metallic "matrix" or carbon "matrix" composite structures or laminated and "specially designed software" therefor.

* * * * *

Controls for ECCN 1763A

* * * * *

GLV $ Value Limit: * * *

Commodities Not Eligible for GCT: Composite materials.

* * * * *

Dated: June 14, 1990.

James M. LeMunyon,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 90-14180 Filed 6-19-90; 8:45 am]

BILLING CODE 3510-DT-M

FEDERAL TRADE COMMISSION

16 CFR Part 414

Trade Regulation Rule: Deception as to Transistor Count of Radio Receiving Sets, Including Transceivers

AGENCY: Federal Trade Commission.

ACTION: Notice of repeal of rule.

SUMMARY: The Federal Trade Commission announces the repeal of the trade regulations rule concerning deception as to transistor count of radio receiving sets, including transceivers ("Transistor Rule" or "Rule" (16 CFR part 414)). The Commission has reviewed the rulemaking record and determined that due to changes in technology and marketing the Rule is no longer in the public interest and should be repealed. Accordingly, the Transistor Rule, 16 CFR part 414, is rescinded. This notice contains a Statement of Basis and Purpose for the repeal of the Rule which incorporates a regulatory analysis.

EFFECTIVE DATE: June 20, 1990.

ADDRESSES: Requests for copies of the Statement of Basis and Purpose should be sent to the Public Reference Branch, Federal Trade Commission, 6th Street and Pennsylvania Avenue, NW., Washington, DC 20580.

FOR FURTHER INFORMATION CONTACT: Robert E. Easton, Esq., Special Assistant—Enforcement, (202) 326–3029, Bureau of Consumer Protection, Federal Trade Commission, Washington, DC 20580.

Statement of Basis and Purpose

Background

The trade regulation rule concerning deception as to transistor count of radio receiving sets, including transceivers, hereafter referred to as the Transistor Rule or Rule, was promulgated in 1968. In essence, the Transistor Rule declares that it is an unfair method of competition and an unfair or deceptive act or practice in connection with the sale of radio receiving sets including transceivers to represent directly or by implication that a radio set contains a specified number of transistors when the transistors counted do not function to detect, amplify or receive radio signals.

During its investigation, staff learned that a transistor is an electronic part that, among other things, can be used to detect, amplify and receive radio signals in radios and walkie-talkies (transceivers). Transistors can perform the same basic functions as electron vacuum tubes in radio devices while producing less heat and being more compact.

Staff further learned that in the 1960's, because of the advantages of transistors, manufacturers of radio devices phased out electron vacuum tubes and used transistors instead. In the 1960's transistors were considered the "new technology" and marketers of consumer radio devices advertised the number of transistors a radio contained to promote sales.

Staff ascertained that in the 1970's, a newly developed technology using integrated circuits (silicon chips) was applied to consumer radio devices. These integrated circuits perform many of the same functions as do transistors in radios and are far smaller. While not totally replacing the use of transistors in radios, integrated circuitry became the new wave of technology.

In the Transistor Rule's Statement of Basis and Purpose, the Commission stated that marketers of radios were using the number of transistors contained in radios as a selling tool. In the Commission's view, the purchasing public believed that the greater the number of transistors in a radio "the better and more powerful the radio." (16 CFR 414.4(a).

The Commission found that certain marketers of radios were advertising and otherwise representing that their products contained specific numbers of transistors when in fact at least some of the transistors being counted were not used to detect, amplify or receive radio signals. Some of the transistors being counted were non-functioning (dummy) or were used for other purposes. 16 CFR 414.1.

Because the Commission concluded that the public perceived that the higher the transistor count the better and more desirable the radio, the Commission determined that it was deceptive to include in a count transistors which did not detect, amplify or receive radio signals. 16 CFR 414.4(b). The Rule forbade making direct or implied representations of transistor count using this deceptive method of counting transistors. 16 CFR 414.6.

The Rulemaking Record

The rulemaking record in this proceeding consists of staff's reports of its inquiry dated April 18, 1988 and May 6, 1988; the Advance Notice of Proposed Rulemaking (54 FR 5090, February 1, 1989); a comment from the Electronic Industries Association (EIA) dated March 3, 1989; staff's report of March 22, 1989; the Notice of Proposed Rulemaking (54 24191, June 6, 1989); staff's final report dated November 16, 1989 and the Presiding Officer's report dated December 19, 1989. The only evidence in the record consists of staff memoranda and the EIA comment.

Analysis of the Rulemaking Record

The Transistor Rule is premised upon concerns relating to the deceptive promotional use of transistor count which the rulemaking record indicates no longer exists. Specifically, modern radios and transceivers use far fewer transistors than when the rule was promulgated and sellers of such products do not use transistor count in advertisements or other marketing activities.

In its informal investigation, staff visited outlets of Radio Shack, Best, Bell, Circuit City and Luskin's and looked at the radios and walkie-talkies in stock. Staff talked with sales personnel at the store and reviewed the Radio Shack, Best, Bell and Evans catalogs. Further, staff spoke with the vice president of the consumer electronics group of the Electronic Industries Association, an organization representing the major manufacturers of electronic products including radios.

Based on staff's inquiry it appears that:

1—Most radios and transceivers use very few transistors. When they are used they mainly form part of the tuning system. Some systems use transistors to run the speakers.

2—Radios and transceivers rely primarily on integrated circuits for detection, amplification and reception of radio signals.

3—Not one of the more than 100 radios and transceivers examined in the stores was marked with or otherwise disclosed the number of transistors contained therein.

4—Only one salesperson even knew of whether or not any of the radios or transceivers contained transistors.

5—The salepersons touted the use of the most modern integrated circuitry in their products.

6—Not one of the hundreds of advertisements for radios and transceivers in the catalogs reviewed mentioned the word transistor.

7—The vice president of EIA stated to staff that transistor use in radios is old technology. He felt that transistors had "no glamour" and were not a selling point today as they were in the 1960's. He said that he frequently reads ads for radios and cannot recall the last time an ad mentioned transistors. Staff Memorandum of April 18, 1988 (R–B–1).

The EIA filed the sole comment in this preceeding. Its comment stated:

EIA, as the associational representative of manufacturers of consumer electronics products including audio systems, tuners,

compact disc players, loudspeakers and other consumer audio products, has received little industry interest in the FTC repeal or non-repeal of this rule.

This lack of interest reflects the fact that transistor counts are rarely, if ever, used in the consumer electronics industry as a means of marketing audio products. Some products may still use transistors but most rely on solid state componentry. Transistors are no longer considered a selling feature for audio electronics products.

Although we believe the rule imposes minimal costs, if any, on manufacturers, it does not appear to have any benefits. Accordingly, it should be eliminated in the interest of efficient government. Comment of Gary Shapiro, March 3, 1989 R-Comment #1.

The Commission concludes that there is substantial evidence in the rulemaking record that the Rule serves no present function. Therefore, the Commission has determined to repeal the Rule. The Commission has followed the procedures set forth in section 18 of the Federal Trade Commission Act (15 U.S.C. 57a) in conducting this proceeding for repeal of the Rule.

Final Regulatory Analysis

The following discussion constitutes the Commission's Final Regulatory Analysis of the proposed repeal of the Rule pursuant to the Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.* and section 22 of the Federal Trade Commission Act, 15 U.S.C. 57b-3.

A description of the reasons why action is being considered and the objectives of and legal basis for the repeal of the Rule have been explained in prior parts of this Statement of Basis and Purpose.

Repeal of the Rule would appear to have little or no effect on any business. Because of changes in technology, it appears that small businesses no longer use transistor count as a method for marketing radios.

The Transistor Rule contains no information collection requirements as defined by the Paperwork Reduction Act, 44 U.S.C. 3501–3518. Repeal of the rule would remove any other compliance requirements that are associated with the Rule.

The only significant alternative to repeal of the Rule is to take no action. Because of advances in technology, the Rule no longer serves a meaningful purpose. Under these circumstances, retaining the Rule would run counter to the efficiencies of repealing rules that no longer serve a useful purpose.

The benefits of the repeal of this Rule result from the removal of an unnecessary and irrelevant regulation from the Code of Federal Regulations (CFR) and from increasing public respect for and observance of the law.

Although the Rule does not appear to be having any current effect in the marketplace, it is prudent to eliminate such unnecessary verbiage from the CFR. Reducing the length of the CFR by several pages each year from now into the future is a consideration.

There are intangible benefits of repealing outdated regulations. These benefits are to be found in the area of respect for the government and laws. There is a benefit for law enforcement in retaining only rules that continue to serve a demonstrable public purpose.

The Commission believes that the above benefits are sufficient to support its determination to rescind this Rule.

List of Subjects in 16 CFR Part 414

Transistors, Trade practices.

PART 414—[REMOVED]

The Commission, under its authority, section 18 of the Federal Trade Commission Act, as amended (15 U.S.C. 57a) amends chapter I of title 16 of the Code of Federal Regulations by removing part 414.

By directions of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 90–14247 Filed 6–19–90; 8:45 am]

BILLING CODE 6750-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 381

Revision of Formula for Determining Filing Fees

[Docket No. RM90–2–000, Order No. 521–A]

Issued June 13, 1990.

AGENCY: Federal Energy Regulatory Commission (Commission).

ACTION: Final rule.

SUMMARY: The Federal Energy Regulatory Commission is adopting in its final rule a revision of the formula for determining the annual adjustment of filing fees in § 381.104(c) of the regulations. Under these regulations, as adopted on an interim basis in Order No. 521, the Commission will average the three previous years' data to determine the annual filing fee for a fee category. This revision will help to reduce wide fluctuations in filings fees from year to year.

EFFECTIVE DATE: This final rule is effective June 13, 1990.

FOR FURTHER INFORMATION CONTACT: Julia Lake White, Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, (202) 208–0457.

SUPPLEMENTARY INFORMATION: In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in Room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

The Commission Issuance Posting System (CIPS), an electronic bulletin board service, provides access to the texts of formal documents issued by the Commission. CIPS is available at no charge to the user and may be accessed using a personal computer with a modem by dialing (202) 208–1397. To access CIPS, set your communications software to use 300, 1200 or 2400 baud, full duplex, no parity, 8 data bits, and 1 stop bit. The full text of this final rule will be available on CIPS for 30 days from the date of issuance. The complete text on diskette in WordPerfect format may also be purchased from the Commission's copy contractor, La Dorn Systems Corporation, also located in Room 3308, 941 North Capitol Street, NE., Washington, DC 20426. In addition to publishing the full text of this document in the **Federal Register**, the Commission also provides all interested persons an opportunity to inspect or copy the contents of this document during normal business hours in Room 3308, 941 North Capitol Street, NE., Washington, DC 20426.

Before Commissioners: Martin L. Allday, Chairman; Charles A. Trabandt, Elizabeth Ann Moler and Jerry J. Langdon.

Final Rule

Issued June 13, 1990.

I. Introduction

The Federal Energy Regulatory Commission (Commission) is adopting as final a revision of the formula for determining the annual adjustment of filing fees in § 381.104(c) of the regulations. Under the regulations adopted on an interim basis in Order No. 521, the Commission will average the three previous years' data to determine the annual filing fee for a fee category.[1] The Commission is adopting this final rule without any changes.

[1] 55 F.R. 12,169 (Apr. 2, 1990); III FERC Stats & Regs. ¶ 30,884 (Mar. 23, 1990).

II. Background and Discussion

Prior to Order No. 521, the Commission's filing fees were updated annually using a formula based on the actual workmonths dedicated to a given fee category for the previous fiscal year, divided by the number of actual completions in the previous fiscal year, multiplied by the average cost per workmonth in the previous fiscal year.[2]

The Commission noted in Order No. 521 that using the formula to determine the fiscal year 1990 filing fees based on 1989 fiscal year data would establish filing fees for certain categories that would be out of line with the purposes underlying the Commission's fee program. The Commission recognized that a problem of wide fluctuations in fees arises when workmonths and completions fluctuate, and when the number of filings is comparatively small.

The Commission concluded that the breadth of the fluctuations could be reduced considerably by using a wider data base for calculations, so as to have the basis overlap each year. The Commission revised the formula for determining the annual update of the filing fees in § 381.104(c) of its regulations to permit averaging three previous fiscal years' data to determine the annual filing fee for a fee category. The Commission issued an interim rule revising § 381.104(c) in order to provide an immediate generic remedy and to avoid imposition of some unfair or inequitable filing fees.

The Commission sought comments on the interim rule due on or before May 2, 1990. Comments were filed by Northern States Power Company (Minnesota) and Northern States Power Company (Wisconsin); Cincinnati Gas & Electric Company; and Public Systems. The commenters generally supported the Commission's action in the interim rule. Northern States argued, further, that the Commission should adopt a multi-tier fee structure for electric rate filings that would more closely track the work involved in processing the individual dockets.[3] Public Systems was disappointed that the Commission had not yet taken action on the current two-class electric rate filing fees system in § 381.502 of the Commission's regulations.[4] Public Systems' support for the interim rule in Order No. 521 was subject to the understanding that the right to timely protest the annual 1989 and 1990 annual fee updates is reserved. Accordingly, Public Systems proposed that a provision be added to 18 CFR 381.104 specifying that, where a timely appeal of an order issued pursuant to that section has been filed, the new fees so challenged will take effect subject to refund.

The Commission declines to adopt the commenters' proposals. The Commission is addressing the electric rate filing fees system in § 381.502 of the regulations in a notice of proposed rulemaking in Docket No. RM87–26–002, issued on May 24, 1990.[5] The commenters' proposals are beyond the scope of the rulemaking in this Docket No. RM90–2–000. In any event, in response to Public Systems we note that substitution of a three-year averaging formula for the previous formula does not in any way affect any rights any person may have to protest the annual filing fee updates.

This final rule is effective June 13, 1990.

III. Regulatory Flexibility Act Certification

The Regulatory Flexibility Act (RFA)[6] generally requires a description and analysis of rules that will have a significant economic impact on a substantial number of small entities.

The revised fees adopted in the rule may have a significant impact on a substantial number of small entities. In effect, the Commission's rule will lessen the economic impact of certain filing fees that would otherwise fluctuate too high. The revised formula will permit a more modest increased or even a decrease in the fees that will be more equitable for all the filing fees. The Commission believes, therefore, that this rule will have in the aggregate a beneficial impact on small entities rather than a negative impact. The Commission concludes, therefore, that this impact will not be "significant" within the meaning of the RFA. Accordingly, the Commission certifies that this rule will not have a "significant economic impact on a substantial number of small entities".

IV. Environmental Statement

The Commission concludes that promulgating this rule does not represent a major federal action having a significant adverse effect on the human environment under the Commission's regulations implementing the National Environmental Policy Act.[7] This rule is procedural in nature and therefore falls within the categorical exemptions provided in the Commission's regulations. Consequently, neither an environmental impact statement nor an environmental assessment are required.[8]

List of Subjects in 18 CFR Part 381

Natural gas, Reporting and recordkeeping requirements.

In consideration of the foregoing, the Commission amends part 381, chapter I, title 18 of the Code of Federal Regulations as set forth below.

By the Commission.

Lois D. Cashell,

Secretary.

PART 381—FEES

1. The authority citation for part 381 is revised to read as follows:

Authority: Department of Energy Organization Act, 42 U.S.C. 7101–7352 (1982); E.O. 12009, 3 CFR 1978 Comp., p. 142; Independent Offices Appropriations Act, 31 U.S.C. 9701 (1982); Natural Gas Act, 15 U.S.C. 717–717w (1988); Federal Power Act, 16 U.S.C. 791–828c (1988); Public Utility Regulatory Policies Act, 16 U.S.C. 2601–2645 (1988);

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[2] *See* former 18 CFR 381.104(c). Under the formula, the workmonths reported for a class of docketed activity were added to that class's pro-rata share of the workmonths reported for relevant support activities. This figure, representing the total number of workmonths dedicated to a class of docketed activity for a year, was divided by the number of completions for that year for the given activity. The resulting quotient represented the average amount of time required to complete one proceeding in that given class of docketed activity. Next, the average cost of a workmonth was calculated based on the Commission's fiscal year actual costs. Then, in order to determine the fee for a given class of activity, the average cost per workmonth was multiplied by the average amount of time, measured in workmonths, required to complete one proceeding in that class.

[3] In Order No. 494, issued April 6, 1988, the Commission adopted the present two-class fee schedule system for electric rate filings made pursuant to sections 205 and 206 of the Federal Power Act. *See* 53 FR 15,374 (Apr. 29, 1988), III FERC Stats. & Regs. ¶ 30,809 (1988) (codified at 18 CFR 381.502). Order No. 494 was appealed to the U.S. Court of Appeals for the District of Columbia Circuit *sub nom. Central Illinois Public Service Co. v. FERC*, No. 88–1545. In response to a motion by the Commission on July 11, 1989, the court remanded Order No. 494 for further consideration. Commission action on the two class fee schedule system is pending on the remand.

[4] On April 21, 1989, Public Systems filed an appeal of staff action (styled as a petition for rehearing) of the 1989 annual notice of update of filing fees in nine dockets numbered RM82–25–003, *et al.*, 54 FR 12,900 (Mar. 29, 1989); III FERC Stats. & Regs. ¶ 20,850 (Mar. 24, 1989). In response to the appeal, on May 22, 1989, the Commission issued a notice of intent to act. Final Commission action on Public Systems' appeal is still pending.

In addition, Public Systems, on May 1, 1990, and, jointly, Central Illinois Public Service Co., Central Power and Light Co., Commonwealth Edison Co., Southwestern Electric Power Co. and West Texas Utilities Co. on May 9, 1990, filed appeals of staff action of the 1990 annual update of filing fees in docket RM90–5–000. *See* 55 FR 13,899 (Apr. 13, 1990); III FERC Stats. & Regs. ¶ 30,885 (Apr. 9, 1990).

[5] 55 FR 22,808 (June 4, 1990); IV FERC Stats. & Regs. ¶ 61,211, (May 24, 1990).

[6] 5 U.S.C. 601–612 (1988).

[7] 52 FR 47,897 (Dec. 17, 1987), III FERC Stats. & Regs. ¶ 30,783 (Dec. 10, 1987) (*codified at* 18 CFR part 380).

[8] *See* 18 CFR § 380.4(a)(1) (1989).

Interstate Commerce Act, 49 U.S.C. 1–27 (1976); Omnibus Budget Reconciliation Act of 1986, Pub. L. 99–509, Title III, Subtitle E, sec. 3401 (October 21, 1986).

2. The interim rule amending 18 CFR part 381 which was published at 55 FR 12,169 on April 2, 1990, is adopted as a final rule without change.

[FR Doc. 90–14190 Filed 6–19–90; 8:45 am]

BILLING CODE 6717–01–M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 24

Current IRS Interest Rate Used in Calculating Interest on Overdue Accounts and Refunds

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Notice of calculation of interest.

SUMMARY: This notice advises the public of the interest rates for overpayments and underpayments of Customs duties. The rates are 11 percent for underpayments and 10 percent for overpayments for the quarter beginning July 1, 1990. This notice is being published for the convenience of the importing public and Customs personnel.

EFFECTIVE DATE: July 1, 1990.

FOR FURTHER INFORMATION CONTACT: Robert B. Hamilton, Jr., Revenue Branch, National Finance Center (317) 298–1245.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to 19 U.S.C. 1505 and Treasury Decision 85–93, published in the **Federal Register** on May 29, 1985 (50 FR 21832), the interest rate paid on applicable overpayments or underpayments of Customs duties shall be in accordance with the Internal Revenue Code rate established under 26 U.S.C. 6621. Interest rates are determined based on the short-term federal rate. The interest rate that Treasury pays on overpayments will be the short-term Federal rate plus 2 percentage points. The interest rate paid to the Treasury for underpayments will be the short-term Federal rate plus 3 percentage points. The rates will be rounded to the nearest full percentage.

The interest rates are determined by the Internal Revenue Service on behalf of the Secretary of the Treasury based on the average market yield on outstanding marketable obligations of the U.S. with remaining periods to maturity of 3 years or less and are to fluctuate quarterly. The rates are determined during the first month of a calendar quarter and become effective for the following quarter.

The rates of interest for the period of July 1, 1990–September 30, 1990, are 10 percent for overypayments and 11 percent for underpayments. These rates will remain in effect through September 30, 1990, and are subject to change on October 1, 1990.

Dated: June 14, 1990.

Carol Hallett,

Commissioner of Customs.

[FR Doc. 90–14183 Filed 6–19–90; 8:45 am]

BILLING CODE 4820–02–M

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. S–210]

RIN 1218–AA72

Welding, Cutting and Brazing

AGENCY: Occupational Safety and Health Administration (OSHA), U.S. Department of Labor.

ACTION: Final rule; technical amendments.

SUMMARY: Three references to OSHA's general industry welding, cutting and brazing standards that are found in other OSHA general industry standards are being amended. These technical amendments are necessary to conform to the April 11, 1990, "Redesignation and other non-substantive revisions" made to the welding, cutting and brazing standards. The references will now reflect the new welding, cutting and brazing rule designations and will not alter the general industry provisions' requirements.

EFFECTIVE DATES: June 20, 1990.

FOR FURTHER INFORMATION CONTACT: Mr. James F. Foster, Office of Information and Consumer Affairs, Occupational Safety and Health Administration, U.S. Department of Labor, Room N3467, 200 Constitution Ave. NW., Washington, DC 20210, (202) 523–8151. This document was principally prepared by Wendell Glasier, Directorate of Safety Standards Programs.

SUPPLEMENTARY INFORMATION: On April 11, 1990 (55 FR 13694) OSHA published a final rule, "Redesignation and other non-substantive revisions" of the OSHA general industry welding, cutting and brazing standards. That action, while not affecting the substance of the standards, renumbered most of the standards' sections and paragraphs in a reorganization.

As discussed below, three references to the general industry welding, cutting and brazing standards which are found in other general industry standards were not corrected in the April 11, 1990 final rule. This action serves to amend those references so that they refer to the proper provisions of the OSHA general industry welding, cutting and brazing standards.

One such reference to the welding, cutting and brazing provisions is in OSHA's standards applicable to storage and handling of liquefied petroleum gases, 29 CFR 1910.110(i)(2)(iii). The liquefied petroleum gas standard referenced the welding and cutting standards contained in 29 CFR 1910.252 regarding the use of liquefied petroleum gas with oxygen. The provisions regarding welding and cutting with oxygen and fuel gases, such as liquefied petroleum gas, were redesignated as § 1910.253. Section 1910.110(i)(2)(iii) is being amended to reflect the new oxygen-fuel gas welding and cutting section number.

The other two references to the welding, cutting and brazing standards are in the standards covering grain handling facilities, 29 CFR 1910.272(f)(2) and appendix A. These provisions concern hot work permits and referenced fire prevention and protection requirements contained in 29 CFR 1910.252(d). Section 1910.252(d) was redesignated as § 1910.252(a), and the grain handling facilities standard's references are being amended accordingly.

OSHA has determined, under the Agency's rules for issuing standards and under the Administrative Procedure Act (APA), that "good cause" exists for issuing these technical amendments to be effective immediately. OSHA is permitted under 29 CFR 1911.5 to issue minor rules or amendments in which the public is not particularly interested without the notice and public procedure which is otherwise mandatory. Likewise, section 553(b)(B) of the APA provides that notice and comment procedures are not required when an Agency finds these procedures are "impracticable, unnecessary, or contrary to the public interest." The APA's requirement that Agency rules be published at least 30 days before their effective date may also be avoided, under section 553(d)(3), if the Agency has "good cause" for doing so. The amendments issued today are minor and technical; they do not affect the

substantive requirements or coverage of the standards themselves. These amendments do not modify or revoke existing rights or obligations, nor do they establish new ones. The amendments are necessary to clearly and properly inform the regulated community of the welding standards currently applicable to them. OSHA concludes, therefore, that rulemaking procedures and delayed effective dates are unnecessary and contrary to the public interest.

List of Subjects in 29 CFR Part 1910

Welding, Occupational safety.

Accordingly, pursuant to sections 4, 6, and 8 of the Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657), 5 U.S.C. 553, Secretary of Labor's Order No. 1–90 (55 FR 9033), and 29 CFR part 1911, title 29, part 1910, of the Code of Federal Regulations is amended as set forth below.

PART 1910—OCCUPATIONAL SAFETY AND HEALTH STANDARDS

1. The authority citation for subpart H of part 1910 is revised to read as follows:

Authority: Sections 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736) or 1–90 (55 FR 9033), as applicable.

Sections 1910.103, 1910.106, 1910.107, 1910.108 and 1910.109 are also issued under 29 CFR part 1911.

Section 1910.110 is also issued under 5 U.S.C. 553 and 29 CFR part 1911.

Section 1910.111 is also issued under 29 CFR part 1911.

Section 1910.120 is also issued under sec. 126 of the Superfund Amendments and Reauthorization Act of 1986 as amended (29 U.S.C. 655 note), 5 U.S.C. 553 and 29 CFR part 1911.

§1910.110 [Amended]

2. In § 1910.110(i)(2)(iii) remove the reference to "§ 1910.252" and add, in its place, a reference to "§ 1910.253".

Subpart R—[Amended]

3. The authority citation for subpart R of part 1910 is revised to read as follows:

Authority: Sections 4, 6, 8, Occupational Safety and Health Act of 1970 (29 U.S.C. 653, 655, 657); Secretary of Labor's Order No. 12–71 (36 FR 8754), 8–76 (41 FR 25059), 9–83 (48 FR 35736) or 1–90 (55 FR 9033), as applicable.

Sections 1910.261, 1910.262, 1910.265, 1910.266, 1910.267, 1910.268 and 1910.269 also issued under 29 CFR part 1911.

Section 1910.272 also issued under 5 U.S.C. 553 and 29 CFR part 1911.

Section 1910.274 and 1910.275 also issued under 29 CFR part 1911.

§1910.272 [Amended]

4. In the first sentence of § 1910.272(f)(2), remove the reference to "§ 1910.252(d)" and add, in its place, a reference to "§ 1910.252(a)".

§1910.272 Appendix A [Amended]

5. In the first sentence of the second paragraph of section 4. *Hot Work Permit*, of appendix A to § 1910.272, remove the reference to "29 CFR 1910.252(d)" and add, in its place, a reference to "29 CFR 1910.252(a)".

Signed at Washington, DC, this 14th day of June, 1990.

Gerard F. Scannell,

Assistant Secretary of Labor.

[FR Doc. 90–14276 Filed 6–19–90; 8:45 am]

BILLING CODE 4510–26–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 15

[GEN Docket No. 87–389, FCC 90–204]

Operation of Radio Frequency Devices Without an Individual License

AGENCY: Federal Communications Commission.

ACTION: Final rule; petition for reconsideration.

SUMMARY: This action responds to a petition for reconsideration of the *First Report and Order* in GEN Docket No. 87–389, 54 FR 17710, April 25, 1989, filed by the Sensormatic Electronics Corporation. The petitioner objects to the Commission's decision to allow new types of devices in the frequency band 902–928 MHz. Because of the potential for interference to its anti-theft field disturbance sensors operating within this band, Sensormatic requests the Commission to permanently preserve the 902–905 MHz band for part 15 devices that were permitted under the former rules or to indefinitely preserve this band but give notice that the Commission plans to revisit this rule in 10 years and may revise it at that time. In response, the Commission is delaying the introduction of new devices operating in the 902–905 MHz band for one additional year.

EFFECTIVE DATE: July 20, 1990.

ADDRESSES: Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: John A. Reed, Office of Engineering and Technology, (202) 653–7313.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's *Memorandum, Opinion and Order* in Gen Docket No. 87–389, FCC 90–204, adopted May 25, 1990 and released June 12, 1990.

The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision also may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857–3800, 2100 M Street, NW., suite 140, Washington, DC 20037.

Summary of the Memorandum, Opinion and Order

1. In the *First Report and Order* in this proceeding, the Commission adopted a comprehensive revision of part 15 of its rules governing the operation of radio frequency devices without an individual license. That action encouraged more effective use of the radio frequency (RF) spectrum while providing additional technical and operational flexibility in the design, manufacture and use of non-licensed devices. As part of this action, the Commission permitted any type of device complying with the established technical standards to operate within the band 902–928 MHz. Previously, only certain types of devices were permitted to operate in this frequency band.

2. The Sensormatic Electronics Corporation (Sensormatic) manufactures anti-theft field disturbance sensors that operate under part 15 in the 902–928 MHz band. These sensors transmit radio frequency signals and detect the reflection of those signals from tags attached to clothing or other articles for which theft protection is desired. Sensormatic, in its petition, indicates concern that the new part 15 devices operating in this band will cause interference to its anti-theft systems, rendering them ineffective. Sensormatic states that interference is likely because new devices would be marketed and demonstrated in shopping malls near where its anti-theft systems are used. It adds that such interference could result in a major increase in the number of items stolen, causing increased costs to consumers. Sensormatic indicates that it currently is developing a new digital microwave system that will be capable of changing frequency if interference is detected.

3. To enable it to resolve interference problems that may occur, Sensormatic requests that new types of part 15 device be prohibited from operation within the 902–905 MHz portion of the 902–928 MHz band. Sensormatic requests that we permanently preserve the 902–905 MHz band for part 15

devices permitted under the former rules or indefinitely preserve this band but give notice that we plan to revisit this rule in 10 years and may revise it at that time.

4. Comments in opposition to the Sensormatic petition were filed by several parties. In general, these comments emphasize the Commission's regulations stating that part 15 devices are not provided protection from interference and that persons operating under part 15 have no vested or recognizable right to the continued use of any given frequency. It was also argued that the lower power permitted for new part 15 devices, relative to the power level of the Sensormatic equipment, would cause the new devices to receive interference long before they themselves could cause interference to the Sensormatic receivers. This petition also drew a large number of Congressional inquiries, some of which indicated concern over potential interference to Sensormatic equipment and others of which stated that granting the Sensormatic request would adversely affect the use of the 902–928 MHz band for new technologies and devices.

5. There is little question that, under the proper circumstances, a device operating in the 902–928 MHz band can interfere with the extremely weak signal reflected from a Sensormatic merchandise tag. It is just as predictable, however, that the Sensormatic transmitter, always on and operating at 100 times the power permitted for the new part 15 devices, is also likely to cause interference to the new devices and at greater distances.

6. Sensormatic's request, that the Commission indefinitely prohibit new part 15 devices in the 902–905 MHz band, does not appear justified. Further, such protection would undermine the basic principles of part 15 operation that part 15 devices must not cause interference and must accept any received interference. We are sensitive, however, to the fact that thousands of Sensormatic systems are installed in stores across the country. Although we believe the interference potential from new part 15 devices will be very slight, we are nonetheless persuaded, out of an abundance of caution, to grant some degree of relief from the immediate implementation of the new rules.

7. We note that Sensormatic indicates that its new system will be available in one to two years. We do not, however, wish to delay the development of new technology and consumer devices for an unnecessarily long period. Thus, we believe that, on balance, the public interest would best be served by delaying the introduction of new devices in the 902–905 MHz band for one year. Combined with the one year since these rules were adopted, Sensormatic will have had adequate opportunity to develop its new equipment.

8. In accordance with the above discussion and pursuant to the authority contained in sections 4(i), 301, 302, and 303 of the Communications Act of 1934, as amended, it *is ordered* That the Petition for Reconsideration filed by Sensormatic Electronics Corporation *is granted* to the extent indicated herein and in all other respects *is denied*. In addition, *it is ordered* that part 15 of the Commission's Rules and Regulations *is amended* as set forth below. These rules and regulations are effective upon 30 days from the date of publication in the **Federal Register**.

List of Subjects in 47 CFR Part 15

Communications equipment, Radio.

Rule Changes

Title 47 of the Code of Federal Regulations, part 15 is amended as follows:

PART 15—[AMENDED]

1. The authority citation for part 15 continues to read as follows:

Authority: Secs. 4, 302, 303, 304, and 307 of the Communications Act of 1934, as amended, 47 U.S.C. Sections 154, 302, 303, 304, and 307.

2. Section 15.37 is amended by adding a new paragraph (d), to read as follows:

§ 15.37 Transition provisions for compliance with the rules.

* * * * *

(d) Prior to May 25, 1991, person shall import, market or operate intentional radiators within the band 902–905 MHz under the provisions of § 15.249. Until that date, the Commission will not issue a grant of equipment authorization for equipment operating under § 15.249 if the equipment is designed to permit operation within the band 902–905 MHz.

3. Section 15.249 is amended by adding a new paragraph (e), to read as follows:

§ 15.249 Operation within the bands 902–928 MHz, 2400–2483.5 MHz, 5725–5875 MHz, and 24.0–24.25 GHz.

* * * * *

(e) Parties considering the manufacture, importation, marketing or operation of equipment under this section should also note the requirement in § 15.37(d).

Federal Communications Commission.

Donna R. Searcy,

Secretary.

[FR Doc. 90–14278 Filed 6–19–90; 8:45 am]

BILLING CODE 6712–01–M

Proposed Rules

Federal Register
Vol. 55, No. 119
Wednesday, June 20, 1990

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Stabilization Conservation Service

Farm Marketing Quotas, Acreage Allotments, and Production Adjustment; Tobacco

7 CFR Parts 723, 724, 725 and 726

AGENCY: Agricultural Stabilization and Conservation Service (ASCS), USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would amend the regulations at 7 CFR parts 723, 724, 725, and 726 which implement the tobacco marketing quota and acreage allotment programs authorized by the Agricultural Adjustment Act of 1938, as amended (the 1938 Act). This proposed rule would remove parts 724, 725, and 726; and would revise part 723 to consolidate current parts 723, 724, 725, and 726. This proposed rule would also delete obsolete and unnecessary provisions. Also, producers of Puerto Rico (type 46) tobacco recently approved marketing quotas for the 1989–1991 crops of tobacco. Thus, this proposed rule would also amend the tobacco marketing quota regulations to include type 46 tobacco. No substantive changes to current regulations are included in this proposed rule.

DATES: Comments must be received on or before July 20, 1990 in order to be assured consideration.

ADDRESSES: Interested persons are invited to submit written comments to: Director, Tobacco and Peanuts Division, ASCS, USDA, P.O. Box 2415, Washington, D.C , 20013. Written comments must be received by July 20, 1990 to be assured consideration. All written submissions made pursuant to this notice will be made available for public inspection in room 5750-South Building, USDA, between the hours of 8:15 a.m. and 4:45 p.m. Monday through Friday.

FOR FURTHER INFORMATION CONTACT: Dennis R. Daniels, Agricultural Program Specialist, Tobacco and Peanuts Division, ASCS, USDA, P.O. Box 2415, Washington, DC, 20013, telephone (202) 447–4281.

SUPPLEMENTARY INFORMATION: This rule has been reviewed under USDA procedures established in accordance with Executive Order 12291 and Department Regulation No. 1512–1 and has been classified as "not major."

It has been determined that this rule will not result in: (1) An annual effect on the economy of $100 million or more; (2) a major increase in costs or prices for consumers, individual industries, Federal, State or local governments, or geographic regions; or (3) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises, to compete with foreign-based enterprises in domestic or export markets.

Information collection requirements contained in this regulation have been approved by OMB under the provisions of 44 USC, chapter 35 and have been assigned OMB #0560–0058 and #0560–0006.

It has been determined that the Regulatory Flexibility Act is not applicable to this proposed rule since the Agricultural Stabilization and Conservation Service (ASCS) is not required by 5 U.S.C. 553 or any other provision of law to publish a notice of proposed rulemaking with respect to the subject matter of this rule.

The title and number of the Federal Assistance Program to which this rule applies are: Commodity Loan and Purchases; 10.051, as found in the catalog of Federal Domestic Assistance.

It has been determined by an environmental evaluation that this action will have no significant impact on the quality of the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is needed.

This program/activity is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with State and local officials. See the notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115 (June 24, 1983).

The regulations in 7 CFR parts 723 through 726 set forth the provisions of the tobacco marketing quota and acreage allotment programs. Part 723 is currently applicable to Cigar-filler (type 41) and Maryland (type 32) tobacco. Part 724 is currently applicable to Fire-cured, Dark air-cured, Virginia sun cured, Cigar-binder (types 51 and 52), Cigar-filler and binder (types 42, 43, 44, 54, and 55) tobacco. Part 725 is currently applicable to Flue cured tobacco and part 726 is currently applicable to Burley tobacco. This proposed rule would revise part 723 and would remove all references to Cigar-binder (types 51 and 52) tobacco in part 724 since marketing quotas are not currently in effect with respect to these kinds of tobacco.

With respect to parts 724, 725, and 726 numerous provisions are identical; accordingly, it has been determined that it would be more efficient to include all tobacco marketing quota and acreage allotment regulations in one part. This consolidation would also result in greater program uniformity and ease in administration. This action would not result in the imposition of additional regulatory provisions. However, obsolete regulations would be deleted under the proposed rule and would not be included in this proposed regulation part 723. This proposed action would result in reduced paperwork and recordkeeping by producers and tobacco industry entities. Although this proposed rule would not impose additional restrictions, comments are requested with respect to proposed provisions of part 723 which the public believes would be unnecessary or which are unclear.

Lists of Subjects in 7 CFR Part 723

Acreage allotments, Marketing quotas, Reporting and recordkeeping requirements, Tobacco.

Proposed Rule

PART 723 [REVISED]

Accordingly, parts 724, 725, and 726 would be removed and the present Part 723 would be revised to read as follows:

PART 723—TOBACCO

Subpart A—General Provisions

Sec.

Sec.

Authority: 7 U.S.C. 1301, 1313, 1314, 1314–1, 1314b, 1314b–1, 1314c, 1363, 1372–75, 1377, 1378 and 1421, Pub. L. 100–387.

Subpart A—General Provisions

§ 723.101 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

The information collection requirements contained in these regulations (7 CFR part 723) have been approved by the Office of Management and Budget (OMB) in accordance with the provisions of U.S.C. chapter 35 and have been assigned OMB control numbers 0560–0058 and 0560–0006.

§ 723.102 Applicability.

The regulations contained in this subpart are applicable to the 1990 and subsequent crops of burley; flue-cured; fire-cured; dark air-cured; Virginia sun-cured; cigar-filler and binder (types 42, 43, 44, 54, and 55); and Cigar filler (type 46) tobacco. These regulations govern the establishment of farm marketing quotas and acreage allotments, the issuance of marketing cards, the identification of marketings of tobacco, the collection and refund of penalties and the keeping of records and making of reports. All of the provisions of these regulations apply to each kind of tobacco for which marketing quotas are in effect unless the wording of the text indicates otherwise.

§ 723.103 Administration.

(a) The regulations in this part will be administered under the general supervision of the Administrator, Agricultural Stabilization and Conservation Service ("ASCS") and shall be carried out in the field by State and county Agricultural Stabilization and Conservation committees ("State and county ASC committees").

(b) State and county ASC committees, and representatives and employees thereof do not have the authority to modify or waive any of the provisions of the regulations of this part.

(c) The State ASC committee shall take any action required by these regulations which has not been taken by the county ASC committee. The State ASC committee shall also:

(1) Correct, or require a county ASC committee to correct any action taken by such county ASC committee which is not in accordance with the regulations of this part, or

(2) Require a county ASC committee to withhold taking any action which is not in accordance with the regulations of this part.

(d) No provision or delegation herein to a State or county ASC committee shall preclude the Administrator, ASCS, or a designee, from determining any question arising under the regulations of this part or from reversing or modifying any determination made by a State or county ASC committee.

(e) To the extent that discretionary authority is not prohibited by statute, the Deputy Administrator—State and County Operations, ASCS ("Deputy Administrator"), may authorize State and county ASC committees to waive or modify deadlines and other requirements of these regulations in order to prevent undue hardship if the Deputy Administrator determines that such action will not affect adversely the operation of the tobacco price support and production adjustment program.

§ 723.104 Definitions.

(a) *Applicability.* The definitions set forth in this section shall be applicable for all purposes of program administration for all kinds of tobacco except as may otherwise be indicated. The definitions in and provisions of parts 718, 719 and 720 of this chapter are

hereby incorporated by reference in these regulations unless the context or subject matter or the provisions of these regulations require otherwise.

(b) *Terms.* The following terms shall be defined as set forth in this paragraph.

Act. The Agricultural Adjustment Act of 1938, as amended.

Active burley tobacco producer. Any person who intends to be a burley tobacco producer in the current year by sharing in the risk of producing the crop and who provides a certification of such intention on a form provided by the Deputy Administrator.

Active flue-cured tobacco producer—(1) Any person who shared in the risk of producing a crop of flue-cured tobacco in at least one of the three years preceding the current year, or

(2) Any person who intends to become a flue-cured tobacco producer in the current year by sharing in the risk of producing the crop and who provides a certification of such intention on a form approved by the Deputy Administrator.

Allowable floor sweepings. The quantity of floor sweepings determined by multiplying 0.0024 times the total producer first sales of the respective kind of tobacco at auction for the season for the warehouse involved.

Auction sale. A marketing of tobacco by a sale at public auction through a warehouse in the regular course of business including sale of all lots of tobacco at public auction in sequence at a given time.

Base Period. The 5 calendar years immediately preceding the year for which farm acreage allotments or marketing quotas are currently being established.

Buyer. A person who engages to any extent in acquiring or marketing tobacco in the form normally marketed by producers.

Buyers corrections account. The warehouse account of tobacco purchased at auction by the buyer but not delivered to the buyer, or any tobacco returned by the buyer, lost ticket, or any other valid reason, which is turned back to the warehouse operator and supported by an adjustment invoice from the buyer. This account shall include the pounds deducted resulting from returned lots, short lots, and short weights, and pounds added resulting from long lots and long weights, which buyers debit or credit to the warehouse operator and support with adjustment invoices.

Carryover tobacco. Tobacco produced prior to the current calendar year which has not been marketed or otherwise disposed of prior to the beginning of the marketing year for the current crop.

Considered planted acreage. An acreage that is used for determining an old farm's history acreage for a kind of tobacco when the acreage planted on the farm to the kind of tobacco in the current year is less than the farm acreage allotment established for such farm in the current year. With respect to:

(1) *Flue-cured tobacco.* If flue-cured tobacco was marketed from the farm during the current year, the considered planted acreage is an acreage determined by subtracting the planted acres from the farm acreage allotment. If flue-cured tobacco was not marketed from the farm in the current year, the considered planted acreage is an acreage, not to exceed the farm's acreage allotment, that is equal to the sum of the acreage:

(i) That could not be planted to flue-cured tobacco because of a natural disaster,

(ii) Computed for pounds leased from the farm,

(iii) In the eminent domain pool,

(iv) Reduced for overmarketing,

(v) Reduced for violation of marketing quota regulations, and

(vi) Converted from the production of flue-cured tobacco during the respective crop year in accordance with part 704 of this title.

(2) *A kind of tobacco other than burley or flue-cured tobacco.* The considered planted acreage for a farm is an acreage, not to exceed the farm's acreage allotment, that is equal to the sum of the acreage:

(i) That could not be planted to the kind of tobacco because of a natural disaster.

(ii) Temporarily transferred from the farm.

(iii) Temporarily released.

(iv) Converted from production of the kind of tobacco in accordance with part 704 of this title.

(v) In the eminent domain pool.

(vi) Reduced for violation of the regulations set forth in this part.

Container. A package in which tobacco is marketed, packed, and stored.

Current crop. The crop planted in the current year.

Current year. The calendar year for which acreage allotments are being established, or tobacco history acreage and yields are being determined, or the farm is being considered under the provisions of the marketing quota program.

Dealer. A person who engages to any extent in acquiring or marketing tobacco in the form normally marketed by producers.

Director. The Director, or Acting Director, Tobacco and Peanuts Division, Agricultural Stabilization and Conservation Service, U.S. Department of Agriculture.

Effective farm acreage allotment. The effective farm acreage allotment for flue-cured tobacco is the allotment determined under § 723.205 of this part.

Effective farm marketing quota. The effective farm marketing quota is the current year farm marketing quota plus or minus any temporary quota adjustments.

Excess tobacco for a farm—(1) *For burley and flue-cured tobacco.* The quantity of tobacco marketed above 103 percent of the effective farm marketing quota.

(2) For kinds of tobacco other than burley or flue-cured. That quantity of tobacco which is equal to the average yield per acre of the entire acreage of tobacco harvested on the farm times the number of acres harvested in excess of the farm acreage allotment, plus any carryover excess tobacco.

Experimental tobacco. Tobacco grown by or under the direction of a publicly owned agricultural experiment station for experimental purposes only.

False Identification. False identification occurs if:

(1) Tobacco was marketed or was permitted to be marketed in any marketing year as having been produced on any farm when, in fact, it was produced on another farm; or

(2) Tobacco was marketed or was permitted to be marketed in any marketing year from a farm and was not identified by a tobacco marketing card for the farm; or

(3) The farm operator or any other producer on a farm permits the use of the tobacco marketing card for the farm to record a marketing of tobacco when, in fact, no tobacco was marketed from the farm.

(4) A tobacco marketing card issued to market a kind of tobacco is used to market another kind of tobacco produced on the same farm.

Family farm corporation. A corporation for which:

(1) Not less than 50 percent of the stock is owned by:

(i) An individual or;

(ii) An individual in combination with:

(A) The spouse of such individual; or

(B) The parent, aunt, uncle, child, grandchild, or cousin of such individual; or

(C) A spouse of any individual specified in paragraph (1)(ii)(B) and;

(2) One or more of the individuals specified in paragraph (1) participates in the direct management of the day to day operations of the corporation.

Farm acreage allotment. For flue-cured tobacco, the allotment established in accordance with § 723.205 of this chapter.

Farm marketing quota—(1) *For burley tobacco, old farms.* The pounds determined by multiplying the preliminary farm marketing quota by the national factor and adjusting the result for any permanent quota adjustment.

(2) *For burley tobacco, new farms.* The pounds for the farm determined by the county ASC committee with the approval of the State ASC committee.

(3) *For flue-cured tobacco.* The pounds determined by multiplying the farm acreage allotment by the farm yield.

(4) *For kinds of tobacco other than burley or flue-cured.* The actual production of tobacco on the farm acreage allotment, which shall be the average yield per acre for the entire acreage of tobacco harvested on the farm times the farm acreage allotment.

Farm yield. The yield determined as provided in § 723.204 of this part.

Floor sweepings. The scraps or leaves of tobacco which accumulate on the warehouse floor in the regular course of business.

Green weight. The weight of tobacco which is in the form normally marketed by farmers prior to being redried, or processed.

Leaf account tobacco. The quantity of tobacco purchased or otherwise acquired by or for the account of a warehouse operator, including floor sweepings purchased from another warehouse operator or dealer, as adjusted by the debits and credits to the buyers correction account. Such quantity shall not include tobacco in the form not normally marketed by producers, including tobacco pickings, and floor sweepings which accumulate on the warehouse floor.

Market. The disposition of tobacco in raw or processed form by voluntary or involuntary sale, barter, or exchange, or by gift between living persons. "Marketing" and "marketed" shall have corresponding meaning to the term "market."

Marketing recorder. Any employee of the U.S. Department of Agriculture, or any employee of an Agricultural Stabilization and Conservation Service county (ASCS) office, whose duties involve the preparation and handling of the records and reports pertaining to the identification of marketing of tobacco.

Marketing year. (1) For flue-cured tobacco, the period beginning July 1 of the current year and ending June 30 of the following year.

(2) For kinds of tobacco other than burley or flue cured. The period beginning October 1 of the current year and ending September 30 of the following year.

New farm. A farm for which an acreage allotment or marketing quota is established for the current year from the national reserve that is set aside for such purpose from the national acreage allotment or marketing quota established for the kind of tobacco.

Nonauction sale. Any first marketing of tobacco other than by a sale at auction.

Old farm.—(1) *For burley tobacco.* A farm which had burley tobacco planted or considered planted in one or more years of the base period.

(2) For of tobacco other than burley. A farm on which there is tobacco history acreage in one or more years of the base period.

Overmarketings. The pounds by which the pounds marketed exceed the effective farm marketing quota.

Planted or considered planted credit. For burley tobacco, credit that is assigned in the current year for a farm with an established farm marketing quota when:

(1) Burley tobacco is planted on the farm.

(2) Quota is:

(i) Leased and transferred from the farm, or

(ii) In the eminent domain pool.

(3) A restrictive lease on federally owned land is in effect prohibiting tobacco production.

(4) Effective quota is zero because of overmarketings or a violation of regulations, or

(5) Acreage is converted from production of burley tobacco in accordance with part 704 of this title.

Pound. The amount of tobacco which, if weighed in its unstemmed form and in the condition in which it is normally marketed by a producer, would equal 1 pound standard weight.

Preceding year. The calendar year immediately preceding the year for which the allotments and quotas are established, or the marketing year preceding the marketing year for which the allotments and quotas are established.

Preliminary farm marketing quota. For burley tobacco, the farm marketing quota for the preceding year.

Preliminary farm yield. For flue-cured tobacco, the yield determined for a farm as provided in § 723.203 of this part.

Processed, Processing. A method of preparing green weight tobacco for storage in which the tobacco may be redried, stemmed, tipped or threshed and the resulting product packed in a container.

Production record. A record prepared by a processor to account for the processing of tobacco.

Quota adjustments. For burley tobacco:

(1) *Temporary.* Adjustments for:

(i) Effective undermarketings,

(ii) Overmarketings from any prior year,

(iii) Reapportioned quota from quota released from farms in the eminent domain pool,

(iv) Ouota transferred by lease or by owner,

(v) Pounds in violation of the regulations for a prior year, and

(vi) Pounds reduced from the burley tobacco quota during the current year in accordance with part 704 of this title.

(2) *Permanent.* Adjustments for:

(i) Old farm adjustment from reserve,

(ii) Pounds of quota transferred to the farm from the eminent domain pool,

(iii) Pounds of quota transferred to or from the farm by sale,

(iv) Pounds of quota transferred to the farm from the forfeiture pool, or

(v) Pounds of forfeited quota.

Resale. The disposition by sale, barter, exchange, or gift between living persons, of tobacco which has been marketed previously.

Sale. The first marketing of tobacco on which the gross amount of the sale price therefor has been or could be readily determined.

Sale date. The date on which the gross amount of the sale price of tobacco is determined.

Sale day. The period at the end of which the warehouse operator bills to buyers the tobacco purchased by them during such period.

Scrap tobacco. The residue which accumulates in the course of preparing tobacco for market, consisting chiefly of portions of tobacco leaves and leaves of poor quality.

Shared in the risk of production. For burley or flue-cured tobacco, involvement in the production of the respective kind of tobacco by a person who:

(1) Invests in the production of a crop of the respective kind of tobacco in an amount which is not less than 20 percent of the proceeds of the sale of the crop;

(2) Depends solely on a share of the proceeds from the marketing of the tobacco for the return on the investment;

(3) Waits until such crop of tobacco is marketed to receive any return on the investment; and

(4) Maintains records, for a period of 3 years after the end of the marketing year in which the tobacco is sold, which may be used to verify that the provisions of this definition have been met.

Strip, scrap, stem. Types of products resulting from processing of tobacco.

Suspended sale. Any marketing of tobacco at auction for which the sale is not identified by a producer marketing card or a dealer's identification card by the end of the sale day on which such marketing occurred.

Tillable cropland. With respect to flue-cured tobacco only, cropland (excluding orchards, vineyards, land devoted to trees, and land being prepared for non-agricultural uses) which the county ASC committee determines can be planted to crops without unusual preparation or cultivation.

Tobacco. Kinds of tobacco that are subject to marketing quotas as follows: Burley tobacco, (type 31); Flue-cured tobacco, (types 11, 12, 13, and 14); Fire-cured tobacco (types 21, 22, and 23); Dark air-cured tobacco (types 35 and 36); Virginia sun-cured tobacco (type 37); Cigar filler (type 46); and Cigar-filler and binder tobacco (types 42, 43, 44, 54, and 55) as classified by the Agricultural Marketing Service at Part 30 of this title.

Tobacco available for marketing. All tobacco produced on a farm which has not been marketed and which has not been disposed of so that it cannot be marketed.

Tobacco in the form not normally marketed by producers. Tobacco leaves, stems, strips, scrap or parts thereof that are the result of green tobacco having been redried, stemmed, tipped, threshed or otherwise processed.

Tobacco pickings. The residue which accumulates in the course of processing tobacco prior to the redrying of such tobacco, consisting of scrap, stems, portions of leaves, and leaves of poor quality shall be considered to be tobacco in the form not normally marketed by producers.

Trucker. A person who trucks, or who otherwise hauls tobacco for a producer, or for any other person.

Undermarketings. For burley or flue-cured tobacco, the actual undermarketings are the pounds by which the effective farm marketing quota is more than the pounds of the respective kind of tobacco marketed, and the effective undermarketings are the smaller of actual undermarketings or the sum of the previous year's farm marketing quota plus pounds of quota temporarily transferred to the farm for the previous year. However, with respect to the 1989 crop, actual undermarketings are the number of pounds by which the effective farm marketing quota is more than the sum of the number of pounds of tobacco marketed and number of pounds for which a disaster payment was made on the 1989 crop of tobacco under part 1477 of this title.

Warehouse operator. A person who engages in the business of holding sales of tobacco at public auction.

§ 723.105 Extent of determinations, computations, and rule for rounding fractions.

(a) *General.* All rounding herein shall be in accordance with the provisions of part 793 of this chapter.

(b) *Allotments.* Farm acreage allotments shall be determined in hundredths of acres.

(c) *Percent excess.* The percentage of excess tobacco available for marketing from a farm, hereinafter referred to as the "percent excess," shall be determined in tenths of a percent.

(d) *Converted rate of penalty.* For tobacco other than burley or flue-cured, the amount of penalty per pound upon marketings of tobacco subject to penalty, hereinafter referred to as the "converted rate of penalty," shall be determined in tenths of a cent.

(e) *Percentage reduction for violation.* A percentage of reduction in an allotment due to a violation shall be determined in tenths of a percent.

(f) *Yields and quotas.* Yields and quotas shall be determined in whole pounds.

§ 723.106 Location of farm for administrative purposes.

The location of a farm in a county for administrative purposes shall be as provided in part 719 of this chapter.

Subpart B—Allotments, Quotas, Yields, Transfers, Release and Reapportionment, History Acreages, and Forfeitures

§ 723.201 Determination of preliminary farm acreage allotments and preliminary farm marketing quotas.

(a) *Flue-cured tobacco.* A preliminary farm acreage allotment shall be determined for the current year for each farm which has flue-cured tobacco history acreage for the base period. The preliminary farm acreage allotment shall be the same as the farm acreage allotment established for the preceding year.

(b) *Burley tobacco.* The preceding year's farm marketing quota shall be the current year's preliminary farm marketing quota for each old farm except that the preliminary farm marketing quota shall be zero if:

(1) The farm or all of cropland has gone out of agricultural production and eminent domain procedure of part 719 of this chapter does not apply.

(2) Quota that was pooled under the provisions of part 719 of this chapter has been canceled.

Tobacco Acreage Allotment and Marketing Quota Regulations 32

(3) A new farm quota that was established in a prior year is canceled.

(c) *Kinds of tobacco other than flue-cured and burley.* A preliminary farm acreage allotment shall be determined for each farm which has tobacco history acreage, as established under paragraph § 723.218 of this part in the base period. If the history acreage for the previous year is the same as the basic allotment, the preliminary allotment shall be the same as the previous year's basic allotment. Otherwise, the preliminary allotment shall be the simple average of the sum of the basic allotment and history acreage for the preceding year.

§ 723.202 Determining farm acreage allotment, except for flue-cured tobacco.

With respect to each kind of tobacco, the preliminary allotments determined for all old farms shall be adjusted uniformly so that the total of such allotments for old farms plus the reserve acreage available for establishing new farm allotments, adjusting inequities in acreage allotments for old farms, and for correcting errors in old farm allotments shall not exceed the national acreage allotment established for such kind of tobacco.

§ 723.203 Determination of flue-cured tobacco preliminary farm yields.

(a) *Old farms.* The preliminary farm yield for a flue-cured tobacco old farm for the current year shall be determined as follows:

(1) *Farm having preliminary farm acreage allotment.* The preliminary farm yield established for the farm shall be the same preliminary farm yield as was in effect for the preceding year.

(2) *Farm not having preliminary farm acreage allotment.* The preliminary farm yield shall be determined by dividing the farm yield by the national yield factor.

(b) *New Farms.* The preliminary farm yield for a new farm shall be determined by dividing the farm yield determined in accordance with § 723.204 of this part for such farm by the national yield factor applicable for the year in which the new farm allotment was established.

§ 723.204 Determination of farm yields and normal yields.

(a) *Flue-cured tobacco.* The farm yield for an old farm shall be determined by multiplying the preliminary farm yield, if the farm has such a yield, by the national yield factor for the current year. The farm yield for new farms and old

farms that do not have a preliminary yield shall be that yield, which the county ASC committee determines for the farm taking into consideration:

(1) The soil and other physical factors affecting the production of tobacco on the farm, and

(2) The farm yields determined for other farms on which the soil and other physical factors affecting the production of tobacco are similar. Tobacco Acreage Allotment and Marketing 0uota Regulations 34

(b) *Burley tobacco.* The farm yield for a farm on which a farm yield has been established shall be the same in the current year as the farm yield previously established for the farm. For any farm not having a previously established yield, the county ASC committee shall establish a yield based on similar farms having a farm yield; however, such yield shall not exceed 3500 pounds.

(c) *All kinds of tobacco except burley.* The normal yield for a farm shall be that yield which the county ASC committee determines is normal for the farm taking into consideration the yields obtained on the farm during any of the years of the base period for which data are available, the soil and other physical factors affecting the production of tobacco on the farm, and the yields obtained on other farms in the locality which are similar with respect to such factors. The normal yield first determined for a farm for any year in accordance with the foregoing provision shall serve as the normal yield for the farm for all purposes in connection with the tobacco marketing program for the year for which such normal yield is determined.

§ 723.205 Determination of farm acreage allotments and effective farm acreage allotments for flue-cured tobacco.

(a) *Farm acreage allotments.* The farm acreage allotment shall be determined by multiplying the national acreage factor as determined by the Secretary for the current year by the preliminary farm acreage allotment for the current year and adjusting the result by:

(1) *Upward adjustment.* Adding the:

(i) Acreage approved in accordance with the provisions of § 723.210 of this part in order to adjust for an inequity or to correct an error;

(ii) Acreage determined by dividing the pounds of quota which are purchased in the current year by the farm yield; and

(iii) Acreage determined by dividing the pounds of forfeited quota which are approved for adjustment from the forfeiture pool by the farm yield.

(2) *Downward Adjustment.* Subtracting the:

(i) Acreage determined by dividing the pounds of quota sold in the current year by the farm yield; and

(ii) Acreage of forfeited allotment.

(b) *Effective farm acreage allotment.* The effective farm acreage allotment for the current year shall be determined by dividing by the effective farm marketing quota by the farm yield.

§ 723.206 Determining farm marketing quotas and effective farm marketing quotas.

(a) *Burley tobacco.* The burley farm marketing quota shall be determined by multiplying the national factor as determined by the Secretary for the current year by the preliminary farm marketing quota for the current year and adjusting the result for permanent quota adjustments.

(b) *Flue-cured tobacco.* The flue-cured farm marketing quota shall be determined by multiplying the farm acreage allotment by the farm yield.

(c) *Burley or flue-cured tobacco.* The effective farm marketing quota shall be the farm marketing quota adjusted by:

(1) *Upward adjustments.* Adding the:

(i) Effective undermarketings from the preceding marketing year,

(ii) The pounds of quota which are temporarily transferred to the farm in the current year.

(2) Downward adjustments. Subtracting the pounds of quota that are:

(i) Overmarketed from the preceding marketing year,

(ii) Overmarketed from any year before the preceding year but have not been subtracted when determining the effective farm marketing quota in a prior year.

(iii) Temporarily transferred from the farm in the current year.

(iv) Reduced in the current year as a result of a violation in a prior year as provided for in § 723.408 of this part.

(vi) Determined, for flue-cured tobacco only, by multiplying the farm yield by the acres reduced from the flue-cured tobacco acreage allotment during the current year in accordance with part 704 of this title.

(vii) For burley tobacco only, designated for reduction under a Conservation Reserve Program contract in accordance with part 704 of this title.

§ 723.207 Determination of acreage allotments or burley marketing quotas for new farms.

(a)(1) *All kinds of tobacco.* The acreage allotment or burley marketing quota established in any crop year for all new farms shall not exceed the national acreage or poundage, as applicable, reserved for new farms for the respective kind of tobacco. The acreage allotment or burley marketing quota for a new farm shall be that acreage or burley marketing quota which the county ASC committee, with the approval of the State ASC committee, determines is fair and reasonable for the farm, taking into consideration the past tobacco experience of the farm operator; the land, labor, and equipment available for the production of tobacco; crop rotation practices; and the soil and other physical factors affecting the production of tobacco. Such acreage allotments or burley marketing quota shall not exceed 50 percent (75 percent for Cigar-filler and Binder tobacco) of the average of the applicable acreage allotments or burley marketing quotas established for two or more but not more than five old farms which are similar with respect to land, labor; and equipment available for the production of tobacco; crop rotation practices; and the soil and other physical factors affecting the production of tobacco; and with respect to flue-cured tobacco acreage allotments, shall not exceed one acre.

(2) *Kinds of tobacco, except burley and flue-cured.* If the acreage planted to tobacco on a new tobacco farm is less than 75 percent of the tobacco acreage allotment otherwise established for the farm pursuant to this section, such allotment shall be automatically reduced to the sum of the tobacco planted acreage and the prevented planted tobacco acreage as determined under Part 718 of this chapter for the farm.

(b)(1) *Written application.* The farm operator must file an application for a new farm acreage allotment or marketing quota at the office of the county ASC committee where the farm is administratively located on or before February 15 of the year for which the new farm acreage allotment or marketing quota is requested.

(2) *Operator requirements.* The operator requesting a new farm acreage allotment or marketing quota must be the sole owner of the farm, except for Cigar-filler and Binder tobacco, the operator need not own the farm. The farm operator shall not own or have an ownership interest in or operate any other farm in the United States for which a tobacco allotment or quota for any kind of tobacco is established for the current year.

(3) *Availability of equipment and facilities.* The operator must own, or have readily available, adequate equipment and any other facilities of production necessary to the production of tobacco on the farm.

(4)(i) *Income from farming.* The operator must expect to obtain during the current year more than 50 percent of the producer's income from the production of agricultural commodities or products. The following shall be considered in computing the operator's income:

(A) *Farm income.* Income from farming shall include the estimated return from home gardens, livestock and livestock products, poultry, or other agricultural products produced for home consumption or other use on the farm(s). The estimated return from the production of the requested new farm allotment or quota shall not be included.

(B) *Non-farm income.* Non-farming income shall include but not limited to salaries, commissions, pensions, social security payments, and unemployment compensation.

(C) *Spousal income.* The spouse's farm and non-farm income shall be included in the computation.

(ii) *Operator a partnership.* If the operator is a partnership, each partner must expect to obtain more than 50 percent of their current year income from farming.

(iii) *Operator a corporation.* If the operator is a corporation, it must have no other major corporate purpose other than ownership or operation of the farm(s). Farming must provide its officers and general manager with more than 50 percent of their expected income. Salaries and dividends from the corporation shall be considered as income from farming.

(iv) *Special provisions for low-income farmers.* The county ASC committee may waive the income provisions in this section provided they determine that the farm operator's income, from both farm and non-farm sources is so low that it will not provide a reasonable standard of living for the operator and the operator's family, and a State ASC committee representative approves such action. In making their determination, the county ASC committee shall consider such factors as size and type of farming operations, estimated net worth, estimated gross family income, estimated family off-farm income, number of dependents, and other factors affecting the individual's ability to provide a reasonable standard of living.

(5) *Experience.* The operator must have had experience in producing, harvesting, and marketing the kind of tobacco requested. Such experience must have been gained by being a sharecropper, tenant, or farm operator (bona fide tobacco production experience gained by a person as a member of a partnership shall be accepted as experience gained in meeting this requirement) during at least 2 of the 5 years immediately preceding the year for which the new farm allotment is requested. The experience must have been gained on a farm having a tobacco allotment for such years for the kind of tobacco requested in the application. However, for Cigar-filler and binder tobacco only, the operator must have experience in any prior year in the production of tobacco as a farm owner, farm operator, sharecropper, tenant, warehouse operator, or laborer on a farm which produced Cigar-filler and binder tobacco.

(6) *Operator has not sold or forfeited allotment.* For flue-cured tobacco only, during the current or the 4 preceding years, the operator must not have sold or forfeited any flue-cured tobacco allotment from any farm.

(c) *Eligibility requirements for the farm.* A new farm acreage allotment or marketing quota may be established if each of the following conditions is met:

(1) Current allotment or quota. The farm must not have on the date of approval of a new farm acreage allotment, an allotment or quota for any kind of tobacco.

(2) *Availability of land, type of soil, and topography.* The available land, type of soil, and topography of the land on the farm must be suitable for tobacco production. Also, continuous production of tobacco must not result in an undue erosion hazard.

(3) *Eminent domain acquisition.* A farm which includes land acquired by an agency having the right of eminent domain for which the entire tobacco allotment was pooled pursuant to part 719 of this chapter, which is subsequently returned to agricultural production shall not be eligible for a new farm allotment or marketing quota for a period of 5 years from the date the former owner was displaced.

(4) *Farm includes land previously having a tobacco acreage allotment.* A farm which includes land which has no tobacco allotment because the owner did not designate an allotment for such land when the parent farm was reconstituted pursuant to part 719 of this chapter shall not be eligible for a new farm acreage allotment for a period of 5 years beginning with the year in which the reconstitution became effective.

(5) *Entire quota sold.* A new farm tobacco acreage allotment may not be established for a farm if, during the current year or the 4 preceding years, the farm was constituted as any part of a farm for which an acreage allotment or marketing quota had been established and for which the current or a former owner sold or permanently transferred all of the tobacco acreage allotment or marketing quota.

(d) *False information.* Any new farm acreage allotment or marketing quota which was determined by the county ASC committee on the basis of incomplete or inaccurate information knowingly furnished by the applicant, shall be canceled by the county ASC committee as of the date the allotment or quota was established. When incomplete or inaccurate information was unknowingly furnished by the applicant, the allotment or quota shall be canceled effective for the current crop year.

(e) *Failure to plant.* A new farm acreage allotment or marketing quota shall be reduced to zero if no tobacco is planted on the farm the first year.

§ 723.208 Determination of acreage allotments, marketing quotas, and yields for divided farms.

(a) *Flue-cured tobacco.* The farm acreage allotment for the divided farm shall be divided pursuant to the provisions of part 719 of this chapter. History acreages and other basic data shall be apportioned among the divided tracts as provided in part 719 of this chapter.

(b) *Burley tobacco.* The farm marketing quota for the divided farm shall be divided pursuant to the provisions of part 719 of this chapter. Other basic data shall be apportioned among the divided tracts the same as the farm marketing quota.

(c) *Burley and flue-cured tobacco.*—(1) *Tract yield.* The tract yield for the tracts divided from a parent farm shall be the same as the tract yield established for the tracts before the division of the parent farm. If a tract is divided, the tract yields for the resulting tracts shall be the same as the tract yield established for the tract before it was divided.

(2) *Single tract farm.* If a tract that is divided from a parent farm becomes a single tract farm, the tract yield shall become the preliminary farm yield and the farm yield for the farm shall be determined by multiplying the preliminary farm yield by the national yield factor for the current year.

(3) *Carryover tobacco.* Where carryover tobacco produced on a parent farm is marketed after the effective date of a reconstitution, such marketings shall be charged to the divided tracts in the same ratio as the marketing quotas are established for the divided tracts or as the county ASC committee determines that:

(1) The proceeds from such marketings are received by the owner or

operator of one or more of the divided tracts, or

(2) The owners of the divided tracts agree.

§ 723.209 Determination of acreage allotments, marketing quotas, and yields for combined farms.

(a) *Burley tobacco.* The farm yield for a combined burley farm shall be the weighted average of the tract yields for the tracts being combined. The weighted average shall be the summation of the extensions of each respective tract's contribution percentage times the tract's yield.

(b) *Flue-cured tobacco.* Flue-cured farm acreage allotments, history acreages, and other basic data for combined farms shall be computed for the base period in accordance with part 719 of this chapter, except that the preliminary farm yield for a combined farm shall be the weighted average of the tract yields for the tracts that comprise the combination. The weighted average shall be the summation of the extensions of the each respective tract's contribution percentage times the tract's yield. The farm yield for the combined farm shall be determined by multiplying the preliminary farm yield for the combined farm by the national yield factor for the current year.

§ 723.210 Corrections of errors and adjusting inequities in acreage allotments and marketing quotas for old farms.

(a)(1) *General.* The allotment or quota for a farm under a long-term land use program agreement shall be given the same consideration under this section as the allotment or quota for any other old farm. Notwithstanding the limitations contained in any other section of this part, the farm acreage allotment or marketing quota for each kind of tobacco established for an old farm may be increased to correct an error or adjust an inequity if the county ASC committee determines, with the approval of a representative of the State ASC committee, that the increase is necessary to establish an allotment or quota for such farm which is fair and equitable in relation to the allotment or quota for other old farms in the county in which the farm is located. Correction of errors shall be made out of that portion of the national reserve held at the national level.

(2) *Burley tobacco.* The reserve for adjusting inequities under this paragraph will be prorated to States based on the relationship of the total of the preliminary farm marketing quotas in each State to the national total of preliminary farm marketing quotas.

(3) *All kinds of tobacco except burley tobacco.* The reserve for adjusting inequities under this paragraph will be prorated to States based on the relationship of the total preliminary farm acreage allotments in each State to the national total of preliminary farm acreage allotments.

(b) *Basis for adjustment.* Increases to adjust inequities in acreage allotments or marketing quotas shall be made on the basis of the past farm acreage, yields, and farm acreage allotments of tobacco, making due allowances for failed acreage and acreage prevented from being planted because of a natural disaster as determined under part 718 of this chapter; land, labor, and equipment available for the production of tobacco; crop rotation practices; and the soil and other physical factors affecting the production of tobacco. The total of all adjustments in old farm allotments or quotas under this paragraph shall not exceed the pounds apportioned to the county for such purpose.

(c)(1) *Burley tobacco.* Adjustments in a farm marketing quota under this paragraph shall become a part of the farm marketing quota.

(2) *Flue-cured tobacco.* Acreage apportioned to a farm under this section becomes a part of the farm acreage allotment. The farm marketing quota for such a farm shall be adjusted by multiplying the adjusted farm acreage allotment by the farm yield.

(3) *All other kinds of tobacco.* For all other kinds of tobacco, acreage approved for a farm under this section becomes a part of the farm acreage allotment.

§ 723.211 Allotments, quotas, and yields for farms acquired under right of eminent domain.

(a) *Determination of acreage allotments and marketing quotas.* The determination of farm acreage allotments and marketing quotas for farms acquired by an agency having the right of eminent domain, the transfer of such allotments or quotas to a pool, and reallocation from the pool shall be administered as provided in part 719 of this chapter. Where all or a part of an allotment or quota is pooled, all or a proportionate part of the farm acreage allotment or marketing quota shall be pooled.

(b) *Closing dates.* The State ASC committee shall establish, in accordance with instructions issued by the Deputy Administrator, a final date for:

(1) *Release.* Releasing pooled farm acreage allotment or farm marketing quota to the county ASC committee for reapportionment to other farms in the county having allotments or quotas for the same kinds of tobacco.

(2) *Request for reapportionment.* Filing a request to receive reapportioned acreage or quota from the county ASC committee for the current year.

(c) *Displaced owner release.* The displaced owner of a farm may, not later than the final release date established by the State ASC committee for the current year, release in writing to the county ASC committee for the current year, all or any part of the acreage allotment or burley tobacco marketing quota for the farm in a pool under part 719 of this chapter for reapportionment for the current year by the county committee to other farms in the county having allotments or marketing quotas for the same kind of tobacco.

(d) *Reapportionment.* The county ASC committee may reapportion, not later than 30 days after the final date established by the State ASC committee for requesting reapportioned acreage or marketing quota for the current year, the released acreage or quota or any part thereof to other farms in the county on the basis of the past farm acreage or marketings and the past farm acreage allotments or quotas for the same kind of tobacco; land, labor, and equipment available for the production of such kind of tobacco; crop rotation practices; and soil and other physical factors affecting the production of such kind of tobacco.

(e) *Effect of reapportionment.* For purposes of establishing future farm allotments or quotas, any reapportioned allotment or quota shall not be considered as planted on the farm to which the allotment or quota was reapportioned.

(f) *Burley or flue-cured tobacco provisions.* For burley or flue-cured tobacco:

(1) *Farm Yield.* The farm yield for a farm to which a pooled marketing quota is transferred shall be determined in accordance with instructions issued by the Deputy Administrator.

(2) *Undermarketings or overmarketings.* The undermarketings of a farm acquired by eminent domain shall be added to the marketing quota for the receiving farm and the overmarketings of the acquired farm shall be subtracted from the marketing quota of the receiving farm.

(3) *Undermarketings while in eminent domain pool.* The pooled quota is considered planted while in the pool. Therefore, for the purpose of determining undermarketings during the time the quota is pooled, the effective quota is considered to be zero.

§ 723.212 Time for making reduction of farm marketing quotas or acreage allotments for violation of the marketing quota or acreage allotment regulations for a prior marketing year.

Any reduction made in a farm acreage allotment or farm marketing quota for the current year for any of the reasons provided for in § 723.408 of this part, shall be made no later than April 1 of the current year in the States of Alabama, Florida, Georgia, North Carolina, South Carolina, and Virginia; or May 1 in all other States. If the reduction cannot be made by such dates for the current year, the reduction shall be made in the farm acreage allotment or farm marketing quota next established for the farm, but no later than by corresponding dates in a later year. No reduction shall be made in the farm acreage allotment or farm marketing quota for any farm for a violation if the farm acreage allotment or marketing quota for such farm for any prior year was reduced because of the same violation.

§ 723.213 Approval of acreage allotments and marketing quotas and notices to farm operators.

(a) *Review by State ASC committee.* All farm yields, acreage allotments, and marketing quotas shall be determined by the county ASC committee of the county in which the farm is located and shall be reviewed by a representative of the State ASC committee.

(b) *Notice to farm operator.* An official notice of the effective farm acreage allotment or farm marketing quota shall be mailed to the operator of each farm shown by the records of the county ASC committee to be entitled to an allotment or quota. The notice to the operator of the farm shall constitute notice to all persons who as operator, landlord, tenant, or sharecropper are interested in the farm for which the allotment or quota is established. Insofar as practicable, all notices shall be mailed in time to be received prior to the date of any tobacco marketing quota or acreage allotment referendum. A copy of such notice containing the date of mailing or a printout summary of such data shall be maintained for not less than 30 days in a conspicuous place in the county ASCS office and shall thereafter be kept available for public inspection in the office of the county ASC committee. A copy of the notice of acreage allotment or marketing quota certified as true and correct shall be furnished without charge to any person interested in the farm for which the allotment or quota is established.

(c) *Mailing notices.*—(1) *All kinds of tobacco.* If the county ASC committee determines that the acreage allotment or farm marketing quota established for any farm may be changed because of,

(i) *Violations.* A violation of the acreage allotment or marketing quota regulations for a prior marketing year,

(ii) *Agricultural production.* Removal of the farm from agricultural production,

(iii) *Farm division.* Division of the farm, or

(iv) *Farm combination.* Combination of the farm, mailing of the notice of such acreage allotment or marketing quota may be delayed, but not later than the date specified in paragraph (c)(2) of this section.

(2) *Time for mailing notices.* The notice of acreage allotment or marketing quota for any farm shall be mailed no later than April 1 of the current year in the States of Alabama, Florida, Georgia, North Carolina, South Carolina, and Virginia or May 1 of the current year in all other States.

(d) *Marketing quota erroneous notice.*—(1) If the official written notice of the farm acreage allotment and marketing quota issued for any farm erroneously stated an acreage allotment or marketing quota larger than the correct effective farm acreage allotment or marketing quota, the acreage allotment or marketing quota shown on the erroneous notice shall be deemed to be the tobacco acreage allotment or marketing quota for the farm for the current year only, if the county ASC committee determines (with the approval of the State Executive Director) that the:

(i) Error was not so gross as to place the operator on notice thereof, and

(ii) Operator, relying upon such notice and acting in good faith, materially changes the operator's position with respect to the production of the crop.

(2) Undermarketings and overmarketings for farms for which the erroneous notice of marketing quota is applied shall be determined based on the correct effective farm marketing quota.

(3) For purposes of determining history acreage the correct acreage allotment shall be used, in determining whether or not 75 percent of the allotment has been planted.

§ 723.214 Application for review.

Any producer who is dissatisfied with the farm acreage allotment and marketing quota established for the producer's farm may, within 15 days after mailing of the official notice of the farm acreage allotment and marketing quota, file application in writing with the county ASCS office to have such allotment and marketing quota reviewed by a review committee in accordance with part 711 of this chapter.

§ 723.215 Transfer of tobacco farm acreage allotment or farm marketing quota that cannot be planted or replanted due to a natural disaster.

(a) *Designation of counties affected by a natural disaster.* The State ASC committee shall determine those counties affected by a natural disaster (including but not limited to hurricane, rain, flash flood, hail, drought, and any other severe weather) which prevents the timely planting or replanting of any of the tobacco acreage allotment or marketing quota for any farm in the county. The county ASC committee of each county affected by the determination shall publicize the determination.

(b) *Application for transfer.* The owner or operator of a farm in a county designated for any year under paragraph (a) of this section may file a written application for transfer of tobacco acreage with the farm acreage allotment or marketing quota for such year to another farm or farms in the same county or in any other nearby county in the same or another State if such acreage cannot be planted or replanted because of the natural disaster determined for such year. The application shall be filed with the county ASC committee for the county in which the farm affected by such disaster is located. If the application involves a transfer to a nearby county, the county ASC committee for the nearby county shall be consulted before action is taken by the county ASC committee receiving the application.

(c)(1) *Amount of burley tobacco transfer.* The burley quota to be transferred shall not exceed the smaller of:

(i) The effective farm quota established under this part less such quota planted to tobacco and not destroyed by the natural disaster, or

(ii) The quota requested to be transferred.

(2) *Amount of transfer for other than burley tobacco.* The allotment to be transferred shall not exceed the smaller of:

(i) The farm allotment established under this part less such acreage planted to tobacco and not destroyed by the natural disaster, or

(ii) The allotment requested to be transferred.

(d) *County ASC committee approval.* The county ASC committee shall approve the transfer if it finds that:

(1) All or part of the farm acreage allotment or marketing quota for the

transferring farm could not be timely planted or replanted because of the natural disaster.

(2) One or more of the producers of tobacco on the transferring farm will be a bona fide producer engaged in the production of tobacco on the receiving farm and will share in the proceeds of the tobacco.

(e) *Cancellation of transfer.* If a transfer is approved under this section and it is later determined that the conditions in paragraph (d) of this section have not been met, the county ASC committee, or the Deputy Administrator may cancel such transfer. Action by the county ASC committee to cancel a transfer shall be subject to the approval of the State ASC committee or its representative.

(f) *Acreage history credits.* Any acreage transferred under this paragraph shall be considered for the purpose of determining future allotments or quotas to have been planted to tobacco on the farm from which such allotment or quota is transferred.

(g) *Closing dates.* The closing date for filing applications for transfers with the county ASC committee shall be July 15 of the current year. Notwithstanding such closing date requirement, the county ASC committee may accept applications filed after the closing date upon a determination by the county ASC committee that the failure to timely file an application was the result of conditions beyond the control of the applicant and a representative of the State ASC committee approves such determination.

§ 723.216 Transfer of tobacco acreage allotment or marketing quota by sale, lease, or owner.

(a) Except with respect to cigar binder (types 54 and 55) tobacco, tobacco acreage allotments or marketing quotas may be transferred between eligible farms in accordance with the provisions of this section.

(1) *Types of transfers.* With respect to:

(i) Cigar filler (type 46) and cigar filler (types 42, 43, and 44), tobacco, transfers may be by lease only.

(ii) Flue-cured tobacco, transfers may be by:

(A) Sale, or

(B) Lease under certain natural disaster conditions provided in this section.

(iii) Burley tobacco, transfers may be by:

(A) Lease,

(B) Owner, or

(C) Sale, when a sale is required to prevent forfeiture of purchased or reallocated quota.

(iv) Fire-cured, dark air-cured, and Virginia sun-cured tobacco, transfers may be by:

(A) Lease,

(B) Owner, or

(C) Sale.

(2) *Transfer agreement.* In order to transfer a marketing quota or allotment between two eligible farms, including a marketing quota or allotment that is pooled in accordance with part 719 of this chapter, the transfer must be recorded on Form ASCS–375 and:

(i) *Where to file.* Filed in the county ASCS office which serves the county in which the transferring farm is located for administrative purposes.

(ii) *Signature-burley tobacco.* Signed by, for burley tobacco only:

(A) *Leases.* The owner and operator of the transferring farm and the owner or operator of the receiving farm.

(B) *Sales.* The owner of the selling farm and an active burley tobacco producer who is the buyer. If the buyer is neither owner nor operator of the farm to which the quota will be assigned, the owner or operator of the farm must give written consent for the quota to be assigned to the farm.

(C) *Owner transfers.* The owner of the transferring farm, who also must be the owner or operator of the receiving farm.

(iii) *Signature-flue-cured tobacco.* Signed by, for flue-cured tobacco only:

(A) *Leases.* The owner of the transferring farm and the owner or operator of the receiving farm.

(B) *Sales.* The owner of the selling farm and an active flue-cured tobacco producer who is the buyer. If the buyer is neither owner nor operator of the farm to which allotment and quota will be assigned, the owner or operator of the farm must be given written consent for the allotment and quota to be assigned to the farm.

(iv) *Signatures—except burley and flue-cured tobacco.* Signed by, for all kinds of tobacco other than burley and flue-cured tobacco, the owner and operator of the transferring farm and the owner or operator of the receiving farm.

(v) *Witness.* Each person whose signature is required by paragraphs (a)(2) (ii), (iii), or (iv) of this section must sign Form ASCS–375 in the presence of a State or county ASC committee member or employee who shall sign Form ASCS–375 as a witness, except that when both the owner and the operator of a transferring farm must sign, such witness is required for the signature of either the owner or operator, but not both. If such signatures cannot be witnessed in the county ASCS office where the farm is administratively located, they may be witnessed in any State or county ASCS office convenient to the owner or operator's residence. The requirement that signatures be witnessed for producers that are ill, infirm, reside in distant areas, or are in similar hardship situations or may be unduly inconvenienced may be waived provided the county ASCS office mails Form ASCS–375 for the required signatures;

(b) *Effective date.* In order for the transfer to be effective for the current year, the Form ASCS–375 shall be filed:

(1) *When to file—burley tobacco.* For burley tobacco:

(i) On or before July 1 of the current year, except as provided in paragraph (b)(1)(ii) of this section. An agreement to transfer quota by lease may be considered to have been filed on July 1 of the current year if such transfer agreement is filed not later than the end of the marketing year that begins during the current year and the county ASC committee, with the concurrence of the State ASC committee, determines that on or before July 1 of the current year the lessee and lessor agreed to such lease and transfer of quota and the failure to file such transfer agreement did not result from gross negligence on the part of any party to such lease and transfer.

(ii) After July 1 of the current crop year and before February 16 of the following calendar year when the transfer is by lease and the transferring farm has suffered a loss of production of burley tobacco due to hail, drought, excessive rain, wind, tornado, or other natural disasters as determined by the Deputy Administrator.

(2) *When to file—flue-cured tobacco.* For flue-cured tobacco:

(i) On or before June 15 if the transfer is by sale.

(ii) After June 30 and on or before November 15 for a transfer by lease when the transferring farm has suffered a loss of production of flue-cured tobacco due to drought, excessive rain, hail, wind, tornado, or other natural disasters as determined by the Deputy Administrator.

(3) *When to file—except burley and flue-cured tobacco.* For all other kinds of tobacco, by the date established by the State ASC committee, except that a lease shall be effective if the county ASC committee, with the approval of a State ASC committee representative, finds that the producer was prevented from timely filing the transfer agreement due to reasons beyond the control of the producer.

(c) *Approval or disapproval.* The county ASC committee or its designee shall approve each transfer agreement that meets the eligibility requirements of

this section. The county ASC committee shall disapprove any transfer agreement that does not meet the eligibility requirement of this section. Any approval or disapproval of a transfer agreement shall to the extent possible be made within 30 days after the transfer agreement is filed with the county ASC committee unless additional time is required as the result of conditions beyond the control of the county ASC committee. However;

(1) *Burley tobacco.* If an agreement is filed after July 1 which provides for the sale of quota, a transfer agreement shall not be approved until the next year's quota is computed for the selling farm. In addition, if marketing quota referendum will be conducted to determine whether or not quotas will be in effect for the crop, a transfer agreement shall not be approved until the Secretary announces that quotas have been approved by referendum.

(2) *Flue-cured tobacco.* If an agreement is filed after June 15 which provides for the sale of an allotment and quota, a transfer agreement shall not be approved until next year's allotment and quota is computed for the selling farm. In addition, if a marketing quota referendum will be conducted to determine whether or not quotas will be in effect for the crop, a transfer agreement shall not be approved until the Secretary announces that quotas have been approved by referendum.

(d) *Time of determination.* An approved transfer agreement shall become effective for the then current crop year, except that if an agreement that is filed after June 15 for the sale of flue-cured tobacco quota or after July 1 for the sale of burley tobacco quota, such approved agreement shall become effective for the next crop year.

(e) *Burley tobacco.* For burley tobacco only:

(1) *Basis for transfer by sale.* If the transfer of a quota is by sale, the transfer shall be based on part or all of the farm poundage quota.

(2) *Basis for transfer by lease or owner.* If the transfer of a quota is by lease or by the owner, transfer shall be based on a part of or all of the effective farm poundage quota.

(3) *Accumulation of quota.* A transfer by lease or by owner shall not be approved if the county ASC committee determines that the primary purpose of the transfer is to accumulate the quota on the farm (i.e., alternately transferring to and from the farm for 2 or more years to maintain the quota without satisfactory evidence of plans for producing the quota on the receiving farm).

(4) *Subleasing.* In order to determine whether there is any subleasing of a burley farm marketing quota, the current year is divided into two periods, the period up to and including July 1, and the period after July 1. The county ASC committee shall not approve a transfer during either period if the effect would be both a transfer to and from the farm during the same period. However, a transfer may be approved within any crop year if quota is transferred from a farm for one or more years and the farm subsequently is combined with another farm that otherwise is eligible to receive quota by lease or by the owner.

(5) *Transferring farm restrictions.* An agreement to transfer quota from a farm by lease or by the owner shall not be approved:

(i) *Limitation.* If the pounds of quota being transferred exceed the difference obtained by subtracting from the effective farm marketing quota the total pounds of quota purchased and/or reallocated from forfeited quota in the current and two preceding years, as adjusted to reflect changes in national quota factors which have occurred since each respective purchase and/or reallocation of quota. However, this provision shall not be applicable to transfer agreements that are filed after July.

(ii) *New farm.* If the farm is a new farm.

(iii) *Reduction pending.* If consideration of a marketing quota violation is pending which may result in a quota reduction for the farm for the current year. However, if the county ASC committee determines that a decision will not be made on the pending case on or before the date specified in § 723.212 of this part, a 1-year transfer will be approved if otherwise eligible.

(iv) *Filed on or before July 1.* Unless the receiving farm is administratively located in the same county as the transferring farm.

(v) *Filed after July 1.* If the transfer agreement is filed after July 1, unless the county ASC committee in the county in which the farm is located for administrative purposes determines that the:

(A) Farm's expected production of burley tobacco is less than 80 percent of the farm's effective marketing quota as a result of a flood, hail, wind, drought, excessive rain, tornado, or other natural disaster.

(B) Acreage planted to burley tobacco on the farm was sufficient to produce, under average conditions, an amount of tobacco which, when added to any carryover tobacco from the previous marketing year, would equal the farm's effective farm marketing quota.

(C) Lessor made reasonable and customary efforts to produce the effective farm marketing quota;

(D) Producers on the farm qualify for price support in accordance with the provisions of Part 1464 of this title; and

(E) Receiving farm is administratively located in the same State as the transferring farm.

(vi) *Consent of lien holder.* For a multiple year transfer, if the farm is subject to lien, unless the lien holder agrees in writing to the transfer; and

(vii) *Claim for marketing quota penalty.* If a claim has been filed against the lessor for a tobacco marketing quota penalty and the claim remains unpaid; However, this provision shall not apply if the claim is paid or the entire proceeds of the lease of the quota are applied against the claim and the county ASC committee determines that the amount paid for the lease represents a reasonable price for the pounds of quota being leased.

(viii) *Forfeiture pending.* To the extent that forfeiture of such quota is expected to become final before July 1.

(6) *Receiving farm restrictions.* An agreement to transfer quota to a farm by lease or by owner shall not be approved:

(i) *Filed on or before July 1.* If the transfer agreement is filed on or before July 1:

(A) Unless the receiving farm is administratively located in the same county as the transferring farm.

(B) If the pounds of quota being transferred to the farm by lease or by the owner exceed the smaller of 15,000 pounds or the difference between the farm marketing quota and one-half the result obtained by multiplying the acres of cropland on the farm by the farm yield.

(ii) *Filed after July 1.* If the transfer agreement is filed after July 1, unless the:

(A) Producers on the farm qualify for price support in accordance with the provisions of part 1464 of this title; and

(B) Pounds of quota to be transferred to the lessee farm do not exceed the difference obtained by subtracting the effective farm marketing quota (before the filing of the transfer agreement) for the lessee farm from the total pounds of tobacco marketed and/or available for marketing (based on estimated pounds of tobacco on hand and/or in the process of being produced) from the farm in the current year.

(C) Transferring farm is administratively located in the same State as the receiving farm.

(7) *Selling farm restrictions.* A transfer of quota from a farm by sale shall not be approved:

(i) *Forfeiture otherwise required.* Unless forfeiture of the quota otherwise would be required. However, this provision may be waived if:

(A) The quota was purchased and/or reallocated to the farm during four preceding years; and

(B) The county ASC committee, with the concurrence of a representative of the State ASC committee, determines that the failure to permit the sale of quota, to the extent otherwise permitted by this section, would cause an undue hardship on the seller and the:

(*1*) Sale is in connection with the settlement of an estate which includes the farm for which the quota was established;

(*2*) Owner of the quota is experiencing financial distress to the extent that current year financing is unlikely;

(*3*) Owner of the quota is disabled due to health reasons to the extent that such person can no longer continue to share in the risk of production of the purchased and/or reallocated quota; or

(*4*) Owner of the quota is sharing in the risk of production as an investing producer and loses resources necessary to produce the crop due to reasons beyond such owner's control such as the loss of a tenant or sharecropper and a replacement can not be obtained.

(ii) *Location of farms.* Unless both the selling farm and the buying farm are administratively located in the same county.

(iii) *Pounds in excess of required forfeiture.* If the pounds of quota being transferred exceed the pounds of quota for which forfeiture otherwise is required.

(iv) *Reduction pending.* If consideration of an indicated marketing quota violation is pending which may result in quota reduction for the farm for the current year. However, if the county ASC committee determines that a decision will not be made on the pending case on or before the date specified in § 723.212 of this part, a transfer will be approved if otherwise eligible.

(v) *Forfeiture pending.* If the agreement for transfer by sale is filed subsequent to the final date which is permitted for the sale of the quota in order to prevent forfeiture.

(vi) *Claim for marketing quota penalty.* If a claim has been filed against the seller for a tobacco marketing quota penalty and the claim remains unpaid: However, this provision shall not be applicable if the claim for such penalty is paid or the entire proceeds of the sale of the quota are applied against the claim and the county ASC committee determines that the amount paid represents a reasonable selling price for the pounds of quota being sold.

(8) *Restrictions on buying farm.* A transfer of quota to a farm by purchase shall not be approved:

(i) *Active producers.* Unless the buyer is an active burley tobacco producer.

(ii) *Cropland limitation.* If the sum of the pounds of quota being transferred, plus the pounds of quota previously transferred to the farm in the current year by lease or by the owner, exceeds the difference between the farm marketing quota and one-half the result obtained by multiplying the acres of cropland on the farm by the farm yield.

(iii) *Quota previously sold.* If the farm owner sold quota from the farm during the current or either of the two preceding years to prevent a forfeiture of the quota.

(iv) Unless both the buying farm and the selling farm are administratively located in the same county.

(9) *Period of transfer.* A transfer by lease or by owner may be for a period of one to five years: However, an agreement to transfer quota by lease shall be limited to the current crop year if the transfer is filed after July 1 in accordance with the natural disaster provisions of this section.

(10) *Redetermination of quota after transfer by lease or by the owner.* After a transfer by lease or by the owner, the effective farm marketing quota shall be redetermined for both the transferring farm and the receiving farm.

(11) *Apportionment of data-selling farm.* The pounds of farm marketing quota retained on the selling farm after the sale of quota shall be divided by the farm marketing quota established for the selling farm before the sale to determine a factor for apportioning farm data. The data to be retained on the selling farm shall be determined by multiplying the factor by the following data:

(i) The amount of any overmarketings which have not been subtracted when a determination is made of the effective farm marketing quota of the selling farm;

(ii) The pounds of quota which have been transferred from the selling farm by lease or by the owner in the current year;

(iii) The pounds of quota which have been reduced in the current year as the result of a marketing quota violation in a prior year;

(iv) The pounds of quota transferred to the farm by lease or by owner in the previous year;

(v) The previous year's farm marketing quota; and

(vi) The previous year's effective farm marketing quota.

(12) *Apportionment of data-buying farm.* The buying farm's share of each respective item of farm data shall be determined by subtracting the pounds which are retained on the selling farm for the respective item from the pounds which were established for the selling farm for the respective item before the current sale of quota. However, the pounds of quota transferred from the selling farm by lease or by the owner and/or the pounds of quota reduction resulting from a marketing quota violation on the selling farm may be apportioned between the farms in accordance with a written agreement between the buyer and the seller if the farm marketing quota retained on the selling farm is sufficient to satisfy the pounds of quota which were transferred by lease or by the owner, the pounds of quota which have been reduced as the result of a marketing quota violation, and the overmarketings for the farm, if any. The data determined in accordance with this paragraph shall he added to any previous data for the buying farm.

(13) *Redetermination Quota after sale or purchase of quota.* After adjusting the data in accordance with the provisions of this section, the effective farm marketing quota shall be determined for both the buying and selling farm.

(14) *Farm division after transfer by lease.* If a farm is divided after there has been a transfer of a marketing quota to the farm by lease, the transferred quota shall be divided in the manner which is designated in writing by the lessee. In the absence of a written designation, the leased quota shall be apportioned in the same manner as the farm marketing quota of the parent farm.

(15) *Multiple year transfer by lease or by owner.* The effective farm marketing quota on a receiving farm having a multiple-year transfer agreement in effect shall be adjusted for each year for which such transfer agreement is in effect to reflect any decrease in the national quota factor which causes the farm marketing quota established for the transferring farm to be less than the pounds of quota which have been transferred to the receiving farm.

(16) *Considered planted credit.* Considered planted credit shall be given to the transferring farm when tobacco quota is transferred from the farm by lease or by owner.

(f) *Flue-cured tobacco.* For flue-cured tobacco only:

(1) *Location of buying and selling farms.* Marketing quota transferred by sale must be to a farm administratively located within the same county.

(2) *Maximum quota to be transferred by sale.* If the transfer is by sale, the

transfer shall be based on part or all of the farm poundage quota. The maximum quota that may be transferred by sale is the farm poundage quota.

(3) *Transfer by lease-involvement of outside parties.* If the transfer is by lease, only the lessor and lessee (or any attorney, trustee, bank, or other agent who regularly represents either the lessor or lessee in business transactions unrelated to the production or marketing of tobacco) may be parties to, or involved in the arrangements for such transfer. The transfer shall be based on a portion or all of the effective farm poundage quota. The maximum quota that may be transferred by lease is the effective farm poundage quota.

(4) *Lessor farm restrictions.* A transfer of quota from a farm by lease shall not be approved:

(i) *New farm.* If the farm is a new farm.

(ii) *Natural disaster.* Unless the county ASC committee in the county in which the farm is located for administrative purposes determines that the:

(A)(*1*) The farm has planted an acreage equal to or more than 90 percent of the effective farm acreage allotment, or

(*2*) In accordance with guidelines issued by the Deputy Administrator, the planted acreage of flue-cured tobacco on the farm is sufficient to produce, under average conditions, an amount of tobacco which, when added to any carryover tobacco from the previous marketing year, would equal the farm's effective farm marketing quota;

(B) Lessor made reasonable and customary efforts to produce the effective farm marketing quota;

(C) Producers on the farm qualify for price support in accordance with the provisions of part 1464 of this title; and

(D) Farm's expected production of flue-cured tobacco is less than 80 percent of the farm's effective marketing quota as a result of a drought, excessive rain, hail, wind, tornado, or other natural disaster as determined by the Deputy Administrator.

(iii) *Claim for tobacco marketing quota penalty.* If a claim has been filed against the lessor for tobacco marketing quota penalty and the claim remains unpaid unless the claim is paid or the entire proceeds of the lease of the allotment and quota are applied against the claim and the county ASC committee determines that the amount of the lease represents a reasonable price for the pounds of quota being leased.

(iv) *Located in the same State.* Unless the lessor farm is administratively located in the same State as the lessee farm.

(5) *Lessee farm restrictions.* A transfer of quota to a farm by lease shall not be approved:

(i) *Price support eligibility.* Unless the producers on the farm qualify for price support under the provisions of part 1464 of this title; and

(ii) *Limitation.* If the pounds of quota to be transferred to the lessee farm exceed the difference obtained by subtracting the effective farm marketing quota (before the filing of the transfer agreement) for the lessee farm from the total pounds of tobacco marketed and/or available for marketing (based on estimated pounds of tobacco on hand and/or in the process of being produced) from the farm in the current year.

(iii) *Located in same State.* Unless the lessee farm is administratively located in the same State as the lessor farm.

(6) *Selling farm restrictions.* A transfer of quota from a farm by sale shall not be approved:

(i) *Previously purchased and/or reallocated quota.* If the farm marketing quota includes quota that was bought, and/or reallocated from the quota which has been forfeited and the purchase and/or reallocation became effective in the 4 preceding years: However, this provision shall not be applicable if:

(A)(*1*) The quota being sold was purchased in such period, if forfeiture of such quota is required by § 723.220 of this part, and the amount of quota being transferred does not exceed the amount of quota for which forfeiture otherwise is required in accordance with the provisions of § 723.220 of this part; or

(*2*) The county ASC committee, with the concurrence of a representative of the State ASC committee, determines that the failure to approve the sale would cause an undue hardship on the seller and:

(B) The sale is in connection with the settlement of an estate which includes the farm for which the quota was established;

(C) The owner of the quota is experiencing financial distress to the extent that current year financing is unlikely;

(D) The owner of the quota is disabled due to health reasons to the extent that such person can no longer continue to share in the risk of production of the purchased and/or reallocated quota; or

(E) The owner of the quota is sharing in the risk of production as an investing producer and loses resources necessary to produce the crop due to reasons beyond such owner's control such as the loss of a tenant or share cropper and a replacement cannot be obtained.

(ii) *Reduction pending.* If consideration of an indicated violation is pending which may result in an allotment and quota reduction for the farm for the current year. However, if the county ASC committee determines that a decision will not be made on the pending case on or before April 1, a transfer may be approved.

(iii) *Forfeiture pending.* If the agreement for transfer by sale is filed subsequent to the final date which is permitted for the sale of the allotment and quota in order to prevent forfeiture.

(iv) *Consent of lien holder.* If the farm is subject to a lien unless the lien holder agrees in writing to the transfer: However, consent of a lien holder is not required for a transfer of the pounds of quota for which forfeiture is required in accordance with the provisions of § 723.220 of this part.

(v) *Claim for marketing quota penalty.* If a claim has been filed against the seller for a tobacco marketing quota penalty and the claim remains unpaid: However, this provision shall not be applicable if the claim for such penalty is paid or the entire proceeds of the sale of the allotment and quota are applied against the claim and the county ASC committee determines that the amount paid represents a reasonable selling price for the pounds of quota being sold.

(vi) *Allotment and quota subject to an approved Conservation Reserve Program contract.* If the allotment and quota is subject to an approved Conservation Reserve Program contract, unless forfeiture otherwise would be required in accordance with the provisions of § 723.220 of this part.

(7) *Buying farm restrictions.* A transfer of quota to a farm by purchase shall not be approved:

(i) *Active producer.* Unless the buyer is an active flue-cured tobacco producer.

(ii) *Tillable cropland limitation.* If the sum of the pounds of quota being transferred, plus the pounds of quota previously transferred to the farm in the current year by lease, exceeds the difference between the farm marketing quota and one-half the result obtained by multiplying the acres of tillable cropland by the farm yield.

(iii) *Quota previously sold.* If the farm owner sold quota from the farm during the current or any of the 4 preceding years or 2 years if such sale was to prevent a forfeiture of the quota.

(iv) *Installment payment option.* Unless the buyer of the flue-cured tobacco acreage allotment and marketing quota has been afforded an option to pay for such allotment and quota in two to five equal annual installments payable each fall beginning

with the fall of the crop year in which the transfer becomes effective and such buyer certifies on a form prescribed by the Deputy Administrator that such option has been made available to the buyer.

(8) *Allotment and quota after transfer by lease.* The effective farm acreage allotment and the effective farm marketing quota shall be determined for both the lessee farm and the lessor farm in accordance with the provisions of §§ 723.205 and 723.206 of this part, respectively.

(9) *Apportionment of data after transfer of quota by sale-selling farm.* The pounds of farm marketing quota retained on the selling farm after the sale of quota shall be divided by the farm marketing quota established for the selling farm before the sale to determine a factor for apportioning farm data for the current year and for the base period. The data to be retained on the selling farm shall be determined by multiplying the factor by the following data:

(i) The planted and considered planted acres for the base period;

(ii) The history acres for the base period;

(iii) The farm acreage allotment for the current year and for the base period;

(iv) The amount of any overmarketings which have not been subtracted when a determination is made of the effective farm marketing quota of the selling farm;

(v) The pounds of quota which have been transferred from the selling farm by lease in the current year;

(vi) The acres of allotment which have been reduced in the current year as the result of a marketing quota violation in a prior year;

(vii) The pounds of quota transferred to the farm by lease in the previous year;

(viii) The previous year's farm marketing quota;

(ix) The previous year's effective farm marketing quota and

(x) The previous year's marketings.

(10) *Apportionment of data-buying farm.* The pounds of farm marketing quota which have been purchased shall be divided by the farm yield for the buying farm in order to determine the farm acreage allotment for the buying farm. The buying farm's share of other farm data shall be determined by subtracting the acres or pounds, as applicable, which are retained on the selling farm from the acres or pounds which were established for the selling farm before the current sale of quota: However, the acres computed for the acres of reduction resulting from a marketing quota violation for the buying farm shall be multiplied by a factor determined by dividing the farm yield of the selling farm by the farm yield of the buying farm in order to determine the acres of reduction from the buying farm for the current year. The pounds of quota transferred from the selling farm by lease and/or the acres of allotment reduction resulting from a marketing quota violation on the selling farm may be apportioned between the farms in accordance with a written agreement between the buyer and the seller if the farm marketing quota retained on the selling farm is sufficient to satisfy the pounds of quota which are leased, the pounds of quota which have been reduced as the result of a marketing quota violation, and the overmarketings for the farm, if any. The data determined in accordance with this paragraph shall be added to any previous data for the buying farm.

(11) *Allotment and quota.* After adjusting the data in accordance with the provisions of this section, the farm acreage allotment, the effective farm acreage allotment, and the effective farm marketing quota shall be determined for both the buying and the selling farm.

(12) *Effect of price support eligibility.* If a lease agreement is filed after the farm operator reports the acreage of tobacco on the farm in the current year, the effective farm acreage allotment which has been determined prior to the approval of the transfer will be used in determining price support eligibility for the farm.

(13) *Violation of lease provisions.* (i) If, after a lease agreement is approved, information is brought to the attention of the county ASC committee which indicates that either the lessor or the lessee, or both, knowingly filed a false certification with respect to a transfer of quota by lease, the county ASC committee shall schedule a hearing, notify such person of the time and place of the hearing, and present evidence at the hearing with respect to the allegation of false certification. If, as a result of the evidence presented, the county ASC committee determines that such person knowingly made a false certification, the county ASC committee shall notify the person of the determination and afford such person 15 days after the mailing of the notice to request a review of the determination by a review committee as provided for by part 711 of this chapter.

(ii) If it is determined that the lessor knowingly made a false certification, the next flue-cured tobacco acreage allotment and marketing quota established for the lessor's farm shall be reduced by that percentage which the leased quota was of the total flue-cured tobacco farm marketing quota established for the farm in the year of the lease.

(iii) If it is determined that the lessee knowingly made a false certification, the lease agreement for purposes of the flue-cured tobacco marketing quota program with respect to the lessee's farm shall be considered to be null and void as of the date approved by the county ASC committee.

(14) *Considered planted credit.* Considered planted credit shall be given to the lessor farm for the tobacco acreage allotment which is deducted as the result of the transfer of quota from the farm by lease.

(15) *Sale of quota with installment payment option.* Notwithstanding any other provision of this section the owner of a farm who sells any flue-cured tobacco acreage allotment and marketing quota may:

(i) Negotiate with more than one prospective buyer before selling such allotment and quota; or

(ii) Sell such allotment and quota to any eligible buyer whom such owner may select; or

(iii) Sell such allotment and quota for a single payment; or

(iv) Include provisions in the agreement of sale to protect the seller's interest if the buyer fails to make full payment. Such provisions may not include the use of such allotment and quota as collateral for purposes of protecting the seller's interest in the allotment and quota.

(v) Flue-cured tobacco acreage allotment and marketing quota purchased in accordance with this subparagraph shall not revert to the seller's farm but shall remain with the farm to which assigned at the time of purchase even though the buyer fails to make full payment to the seller for such allotment and quota.

(g) *Burley and flue-cured tobacco.* For burley or flue-cured tobacco:

(1) *Carryover tobacco.* If tobacco is marketed after the entire farm marketing quota of the producing farm has been transferred by sale, the tobacco shall be considered as having been marketed on each farm to which farm marketing quota was transferred by sale in accordance with a transfer agreement filed after June 15 for flue-cured tobacco, or July 1 for burley tobacco, of the last year in which a farm marketing quota was established for the producing farm. Such marketing shall be prorated to each farm in proportion to the pounds of farm poundage quota purchased by each farm. If there was more than one farm to which a farm marketing quota was transferred by sale, the marketing may

be assigned to the farms in the manner agreed to in writing by each of the buyers of such farm marketing quota.

(2) *Cancellation of transfer.* A transfer of flue-cured allotment and quota, or burley quota, under this section which was approved in error or on the basis of incorrect information furnished by the parties to the agreement shall be canceled by the county ASC committee. For the purpose of determining any overmarketings and undermarketings from the farms, and for the purpose of determining eligibility for price support and marketing quota penalties, the cancellation shall be effective as of the date of approval. However, such cancellation shall not be effective for the current marketing year for price support and marketing quota penalty purposes if the:

(i) Transfer approval was made in error or on the basis of incorrect information which had been unknowingly furnished by the parties to the agreement; and

(ii) Parties to the transfer agreement were not notified of the cancellation before the marketing for the receiving farm exceeded the correct effective farm marketing quota.

(3) *Canceled because of fraud.* If a transfer of a flue-cured allotment and quota, or burley quota, is canceled because of fraud on the part of the owner of the transferring farm but no fraud is attributable to either the owner or operator of the receiving farm, such cancellation shall be effective as of the date of approval of the transfer except for purposes of determining eligibility for price support and marketing quota penalties for the receiving farm. In such case, the overmarketings shall be charged against the farm from which the transfer was made if the farm, after any reconstitution which may be necessary as a result of fraud, is assigned a flue-cured allotment and quota, or burley quota, against which the overmarketings could be charged. Otherwise, the overmarketings shall be charged against any other farm involved in the fraud having a flue-cured allotment and quota, or burley quota, after any reconstitution required by such fraud. Notwithstanding the foregoing, any overmarketings on the receiving farm which are in excess of the amount of quota involved in the canceled transfer shall be charged against the receiving farm.

(4) *Dissolution or revision of a transfer agreement.* A transfer agreement may be dissolved or minor revisions made with respect to such agreement if a written request by all parties to the agreement is made to the county ASC committee by November 15 of the current marketing year for flue-cured tobacco, or by February 15 of the current marketing year for burley tobacco. After any such dissolution or revision of a transfer agreement, an official notice of the flue-cured acreage allotment and marketing quota, or burley quota, shall be issued by the county ASC committee to each of the operators involved in the transfer agreement.

(h) *Cigar tobacco.* For cigar-filler (type 46) and cigar-filler (types 42, 43, and 44) tobacco only, the provisions of paragraph (j) of this section are applicable in addition to the following:

(1) *Farm eligible.* The owner and operator (acting together if different person) of any farm for which an old farm tobacco acreage allotment is established for the current year may lease and transfer all or any part of the farm acreage allotment established for such farm to any other owner or operator of a farm in the same county with a current year's allotment (old or new farm) for the same kind of tobacco for use on such farm. Transfer of allotments by lease shall not exceed 5 years.

(2) *Transfer approved acre per acre.* The lease and transfer shall be approved acre per acre.

(3) *Considered planted credit.* The amount of allotment acreage which is leased from a farm shall be considered for the purpose of determining future allotments (and tobacco history acreage) to have been planted to tobacco on such farm. The amount of allotment acreage which is leased and transferred to a farm shall not be taken into account in establishing allotments for subsequent years for such farms.

(4) *Limitation on acreage transferred.* The total acreage allotted to any farm after the transfer by lease of tobacco acreage allotment to the farm shall not exceed 50 percent of the acreage of cropland in the farm, except that in the case of cigar-filler (types 42, 43, 44, and 46) transfers, such transfers shall be limited to a total of 10 acres.

(5) *Transfer from the pool.* Allotments in a pool pursuant to part 719 of this chapter may be eligible for lease and transfer during the 3-year life of the pooled allotment. An agreement to lease and transfer shall not serve to extend the life of such pooled allotment.

(i) *Fire-cured, Dark air-cured, and Virginia sun-cured tobacco.* For Fire-cured, Dark air-cured, and Virginia sun-cured tobacco, only, the following provisions of this section are applicable in addition to the following:

(1) *Persons eligible to file a record of transfer (ASCS–375)—sale or lease.* The owner and operator of any old farm for which a Fire-cured, Dark air-cured, or Virginia sun-cured tobacco allotment is established for the current year may sell or lease all or any part of such allotment to any other owner or operator of a farm in the same county, and in the same State for Virginia fire-cured (type 21) or Virginia sun-cured (type 37) tobaccos. The receiving farm need not be an old farm. In the case of a permanent transfer, a statement signed by all parties to the transaction confirming that the sale has been made shall be filed with the county ASC committee.

(2) *By owner.* The owner of any old tobacco farm for which a Fire-cured, Dark air-cured, or Virginia sun-cured tobacco allotment is established for the current year may transfer any or all of such allotment permanently, or for a term of years designated by the owner, to another farm in the same county (within the same State for Virginia fire-cured and Virginia sun-cured tobacco) owned or controlled by such owner.

(3) *Maximum period of transfer by lease.* Transfer of allotments by lease shall not exceed 5 years.

(4) *Productivity adjustment-reductions in farm allotments being transferred.* The county ASC committee shall determine a normal yield per acre for each farm from which, and for each farm to which, a tobacco acreage allotment or any part thereof is transferred. (For across county line transfers, the county ASC committee for the county in which each farm is located shall determine the normal yield.) If the normal yield for the farm to which transfer is made for the year the transfer is to take effect exceeds the normal yield for the farm from which the transfer is to take effect by more than 10 percent, the allotment so transferred shall be reduced for differences in farm productivity. The county ASC committee shall determine the amount of allotment to be transferred by sale, lease, and by owner, where productivity adjustment is required under this paragraph as follows:

(i) Multiply the normal yield established for the farm from which the allotment is being transferred by the acreage being transferred, then

(ii) Divide the result by the normal yield established for the farm to which the allotment is to be so transferred. The amount of allotment so transferred from a farm shall be the full amount and the amount of allotment so transferred to a farm shall be the reduced amount. In the case of temporary transfers of allotment for 1 or more years by lease or by owner, the productivity adjustment and amount so transferred shall be redetermined by the county ASC

committee each year the transfer remains in effect.

(5) *Adjustments in farm history acreage.* The farm history acreage for the immediately preceding 5 years on farms from which and to which permanent transfer of allotment is made shall be adjusted by the county ASC committee for each of the base years to correspond with the amount of allotment transferred between the farms. In the case of temporary transfers of allotment for 1 or more years by lease or by owner, the farm history acreage shall not be reduced on the farm from which the transfer is made and farm history acreage shall not be transferred to the receiving farm.

(6) *Limitation on acreage transferred.* The total of the Fire-cured, Dark air-cured, or Virginia sun-cured tobacco allotment which may be transferred for each kind of tobacco, by sale, lease, or by owner, to a farm shall not exceed 10 acres of allotment. However, the total of each acreage for each kind of tobacco allotted to any farm after such transfer (the sum of its own allotment and the acreage transferred after any adjustment in normal yields for the current year) shall not exceed 50 percent of the acreage of cropland on the farm. The cropland in the farm for the current year for purposes of such transfers shall be the total cropland as defined in part 719 of this chapter.

(7) *Prohibition on permanent transfer.* A permanent transfer by sale or by owner shall not be approved from any farm to which an allotment was permanently transferred by sale or by owner within the 3 immediately preceding crop years.

(8) *Temporary transfer to non-owned farm.* A transfer requested on a temporary basis to a farm controlled but not owned by the applicant shall be approved only if the applicant will be the operator of the farm to which the transfer is to be made for each year of the period for which the transfer is requested. When the applicant for whom such transfer has been approved no longer is the operator of the receiving farm due to conditions beyond such operator's control, the transfer shall remain in effect unless the transfer is terminated under the provisions of paragraph (j) of this section. Conditions beyond the operator's control shall include, but not be limited to, death, illness, incompetence, or bankruptcy of such person.

(9) *Transfer of pooled allotment.* Allotments established for a farm as pooled allotment under part 719 of this chapter may be transferred on a:

(i) Permanent basis during the 3-year life of a pooled allotment, or

(ii) Temporary basis for a term of years not to exceed the remaining number of crop years of such 3-year period. A temporary agreement to transfer shall not serve to extend the life of such pooled allotment.

(10) *New farm eligibility.* Any farm from which the entire farm allotment is sold or permanently transferred by the owner shall not be eligible for a new farm tobacco allotment for the kind transferred during the 5 years following the year in which such transfer is made.

(11) *Transfer of history acreage.* Permanent transfer of allotment shall have the effect of transferring history acreage, farm base, and marketing quota attributable to such allotment. In the case of a transfer by lease, the transferred allotment shall be considered for purposes of establishing future allotments to have been planted on the farm from which such allotment was transferred.

(j) *Tobacco except burley, flue-cured, and cigar (types 54 and 55).* For tobacco that may be transferred in accordance with the provisions of paragraph (h) or (i) of this section, the following provisions shall also apply:

(1) *New farm allotment.* A new farm allotment shall not be transferred.

(2) *Tobacco allotment subject to an approved Conservation Reserve Program contract.* A transfer of allotment designated for reduction under a Conservation Reserve Program contract shall not be approved.

(3) *Subleasing prohibited.* A transfer of allotment from a farm shall not be approved during the period for which a current temporary transfer agreement is in effect that transferred quota to the same farm.

(4) *Limitation on transfer to and from a farm in the same year.* If a transfer agreement is in effect for the current crop year for a farm, a transfer of allotment shall not be approved during the same crop year:

(i) From such farm receiving allotment by transfer for such year, or

(ii) To such farm which had allotment transferred from it for such year.

(5) *Farm in violation.* If consideration of a violation is pending which may result in an allotment reduction for a farm for the current year, the county ASC committee shall delay approval of any transfer of allotment from or to the farm until the violation is cleared or the allotment reduction is made. However, if the allotment reduction in such case cannot be made effective for the current crop year before the final date for reducing allotments for violations, the transfer may be approved by the county ASC committee. In any case, if, after a transfer of a tobacco acreage allotment has been approved by the county ASC committee, it is determined that the allotment for the farm from which or to which such acreage is transferred is to be reduced for a violation, the allotment reduction for such farm shall be delayed until the following year.

(6) *Claim for tobacco marketing quota penalty.* A transfer of acreage allotment from a farm shall not be approved if a claim has been filed against the lessor, seller, or transferring owner for a tobacco marketing quota penalty and the claim remains unpaid. However, this provision shall not apply if the claim is paid or the entire proceeds of the lease or sale of the allotment are applied against the claim and the county ASC committee determines that the amount paid for the lease or sale represents a reasonable price for the acres of allotment being transferred.

(7) *Approval after review period.* A transfer of allotment shall not be approved by the county ASC committee for any farm before the time of filing an application for review, as shown on the original allotment notice for the farm, has expired. If an application for review is filed for a farm involved in a transfer agreement, such agreement shall not be approved by the county ASC committee until the allotment for such farm is finally determined pursuant to part 711 of this chapter.

(8) *Acreage allotment after lease and transfer.* The acreage allotment determined after a temporary transfer for a farm under the provisions of this section shall be the allotment of such farm for the current year only for the purpose of determining:

(i) Excess acreage,

(ii) The amount of penalty to be collected on marketings of excess tobacco including absorption of carryover penalty tobacco,

(iii) Eligibility for price support, and

(iv) The farm marketing quota and the percentage reduction for a violation in the allotment for the farm.

(9) *Cancellation of transfer.* Any transfer of allotment under this section which was approved by the county ASC committee in error or on the basis of incorrect information furnished by the parties to the agreement shall be canceled by the county ASC committee. Such cancellation shall be effective as of the date of approval for purposes of determining eligibility for price support and marketing quota penalties except that such cancellation shall not be effective for the current marketing year for price support and marketing quota penalty purposes, if:

(i) The transfer approval was made in error or on the basis of incorrect

information unknowingly furnished by the parties to the transfer agreement; and

(ii) The parties to the transfer agreement were not notified of the cancellation before the tobacco was planted.

(10) *Dissolution or revision.* A transfer agreement may be dissolved or minor revisions made where a request by all parties to the agreement is made in writing to the county ASC committee. Such written notification shall be filed prior to planting the tobacco. A late filed request to dissolve or revise the transfer may be effective for the current year if the county ASC committee with approval of a representative of the State ASC committee determines that the producer was prevented from timely filing for reasons beyond such producer's control.

(11) *Reconstituted farm.* The allotment for a farm being divided or combined in the current year shall be the allotment after the transfer has been approved. Notwithstanding the above, in the case of a division, the county ASC committee shall allocate the acreage that was transferred by lease to the tracts involved in the division as the parent farm owners and operators designate in writing. In the absence of such designation, the county ASC committee shall apportion the leased acreage.

(12) *Consent of lien holder.* A transfer of allotment other than by annual lease shall not be approved from a farm subject to a mortgage or other lien unless the transfer is agreed to in writing by the lien holder.

§ 723.217 Release and reapportionment of old farm acreage allotments for Cigar-filler and Binder (types 42, 43, 44, 54, and 55) tobacco.

(a) *Annual or permanent release of acreage allotments to State committee.* Except as provided in this paragraph, all or any part of a farm acreage allotment on which Cigar-filler and Binder (types 42, 43, 44, 54, and 55) tobacco will not be produced and which the operator of the farm voluntarily releases on an annual basis, or both the owner and operator voluntarily releases on a permanent basis, in writing to the State ASC committee by not later than the final date for filing releases established by the State ASC committee for the current year shall be deducted from the allotment of such farm.

(1) For the farm voluntarily releasing tobacco farm acreage allotment on an annual basis, such acreage will be considered as having been planted on the releasing farm for the purpose of establishing allotments for subsequent years. For the farm receiving such annual released acreage, such acreage shall not be taken into account in establishing future allotments for the farm. The tobacco history acreage for a farm releasing on a permanent basis shall not be taken into account in establishing future allotments for the farm. The tobacco history acreage for a farm releasing on a permanent basis shall be adjusted to reflect the acreage permanently released.

(2) An acreage allotment shall not be released either annually or permanently:

(i) From the eminent domain allotment pool if an application for transfer from the pool has been filed in accordance with part 719 of this chapter;

(ii) From a new farm; or

(iii) To the extent such acreage is designated for reduction under a Conservation Reserve Program contract.

(b) *Reapportionment of released acreage allotment.* The acreage voluntarily released on an annual or permanent basis for the current year may be reapportioned by the State ASC committee to any farm in any county in the State including a farm receiving a new farm allotment. The State ASC committee shall select the counties to which the released acreage will be reapportioned. The county ASC committee shall select the farms to which the released acreage will be reapportioned. The State ASC committee shall keep records on both an annual and permanent basis of the source of acreage released. Any acreage released for the current year on a permanent basis which is not reapportioned by the State ASC committee in the current year may be reapportioned in the following year. The county ASC committee for the county receiving released acreage may reapportion the tobacco allotment acreage on an annual or permanent basis to other farms in the county in amounts determined by the county ASC committee to be fair and reasonable on the basis of land, labor, and equipment available for production of Cigar-filler and binder (types 42, 43, 44, 54, and 55) tobacco; crop rotation practices; and the soil and other physical factors affecting the production of tobacco. Released acreage should not be reapportioned on a temporary or permanent basis to any farm unless there is assurance from the operator to the county ASC committee that the released acreage being received will be produced. Allotment reapportioned to a farm on an annual basis can only be used by the receiving farm for increased production during the current year. Allotment reapportioned to a farm on a permanent basis shall be added to the current year allotment or shall serve to establish an allotment for a farm without a current allotment. A farm shall be eligible to receive reapportionment of released acreage on either or both an annual or permanent basis only if a written request is filed by the farm owner or operator at the office of the county ASC committee not later than the final date for filing such requests established by the State ASC committee for the current year.

§ 723.218 Determining tobacco history acreage.

With respect to each respective kind of tobacco, the tobacco history acreage shall be determined for each farm for which a tobacco acreage allotment was established for such kind of tobacco for the current year.

(a) The history acreage shall be the same as the farm acreage allotment for the respective kind of tobacco if in the current year, or either of the two preceding years, the sum of the planted and considered planted acreage of such kind of tobacco was as much as 75 percent of the farm acreage allotment. Otherwise, the history acreage shall be the sum of the planted and considered planted acreage of such kind of tobacco.

(b) Notwithstanding any other provision of this section, for the respective kind of tobacco, the history acres for the current year and for each year of the base period shall be reduced to zero if:

(1) A new farm allotment was canceled;

(2) The allotment was in a pool established in accordance with the eminent domain provision of part 719 of this chapter and the period of eligibility has expired for transferring the allotment from the pool; or

(3) The county ASC committee determines that the farm has been retired from agricultural production and the allotment is not eligible for pooling in accordance with the eminent domain provisions of part 719 of this chapter.

§ 723.219 Forfeiture of burley tobacco marketing quota.

(a) *Determination of quota subject to forfeiture.* (1) For purposes of paragraph (b) of this section, the phrase "owns a farm" means ownership of:

(i) A farm as constituted under part 719 of this chapter, if the entire farm shares a common ownership; or

(ii) All of the land within a farm which shares a common ownership if the parent farm consists of tracts of land having separate ownerships.

(2) For purposes of paragraph (b) of this section, the county ASC committee shall apportion, in accordance with the provisions of part 719 of this chapter, the burley tobacco quota assigned to a farm

between the various tracts of land which are separately owned by:

(i) A person not using the land on the farm for which a burley tobacco marketing quota is established for agricultural purposes.

(ii) A person who uses the land on the farm for which the burley tobacco marketing quota is established for agricultural purposes or for educational, instructional, or demonstrational purposes.

(3) The farm marketing quota determined under this section for each farm or tract, as applicable, shall be the amount of quota subject to forfeiture under this section.

(b) *Person who does not use the land on the farm for which the marketing quota is established for agricultural purposes or does not use such marketing quota for educational, instructional, or demonstrational purposes.* For purposes of this paragraph, the term "person" means a person as defined in part 719 of this chapter, including any governmental entity, public utility, educational institution, religious institution or joint venture (but not including any farming operation involving only spouses), but excluding any individual.

(1) *Required forfeiture.* With respect to any person owning a farm for which a burley tobacco marketing quota is established, if the county ASC committee determines that such person does not use the land on such farm for agricultural purposes, or does not use such burley tobacco marketing quota for educational, instructional, or demonstrational purposes, such person shall forfeit such quota which is not sold on or before December 1 of the year after any year for which the county ASC committee makes such determination.

(2) *Agricultural purposes.* Land on the farm for which a burley tobacco marketing quota is established shall be considered to be used for agricultural purposes if the county ASC committee determines that:

(i) In the current year or either of the 2 preceding years such land is used for the production of:

(A) Row crops of any type;

(B) Livestock or poultry (including pasture and forage for livestock);

(C) Trees (including orchards and vineyards); or

(D) Hay or native grasses on open land; or

(ii) In the current year such farm is owned by an educational institution which uses such burley tobacco marketing quota solely for educational, instructional, or demonstrational purposes.

(3) *Documentation.* Within 30 days after a written request is made by the county ASC committee, or within such extended time as may be granted by the county ASC committee, a person must submit such documentation as may be requested to support a determination that the provisions of paragraph (b)(1) of this section have been met with respect to such person. Upon failure of such person to timely respond to this request, the county ASC committee shall determine that the person does not use the land on the farm for agricultural purposes, or does not use the burley tobacco marketing quota for educational, instructional, or demonstrational purposes.

(c) *Buyer of quota fails to share in the risk of production*—(1) *Forfeiture required.* If any person buys burley tobacco quota and such person fails to share in the risk of producing the tobacco which was planted subject to such quota during any of the 5-crop years beginning with the crop year for which the purchase became effective, such person shall forfeit the purchased quota if it is not sold on or before December 31 of the year after the crop year in which such crop was planted.

(2) *Failure to utilize purchased quota.* The failure to utilize purchased burley tobacco quota for the production of tobacco shall not result in the forfeiture of such quota, but the 5-year period which is specified in paragraph (c)(1) of this section shall be extended 1 year for each year in which the quota is not utilized.

(3) *Reduction for failure to share in the risk of production.* The effective quota shall be reduced, but not below zero pounds, for leasing and marketing quota purposes only, to the extent of the purchased quota for each crop after the crop year in which the buyer of such quota fails to share in the risk of producing a crop of tobacco which is subject to such quota.

(4) *Determining forfeited amount.* If only part of the quota on a farm is attributable to a purchased quota, the amount of the farm marketing quota which must be forfeited under paragraph (c) of this section shall be determined by increasing or decreasing each respective purchase of farm marketing quota for the farm to reflect changes in national quota factors since the purchase occurred and subtracting the pounds of quota which have been sold to prevent forfeiture.

(d) *Hearing.* Before any forfeiture of quota becomes effective under the provisions of this section, the county ASC committee shall:

(1) Schedule a hearing for the affected person.

(2) Notify the affected person of the hearing at least 10 days in advance of the hearing.

(3) Make a determination, on the basis of the evidence presented at the hearing by or on behalf of the affected person and by or on behalf of the county ASC committee as to whether or not:

(i) Any of the conditions for forfeiture specified in this section exist; and

(ii) The affected person knowingly failed to take steps to prevent forfeiture of allotment and quota when such forfeiture conditions have been determined to exist with respect to the provisions of paragraph (b) of this section.

(4) Notify the affected persons of the county ASC committee determination and, if forfeiture of quota is to be required, afford such person an opportunity to appeal to a review committee in accordance with the provision of part 711 of this chapter.

(e) *Apportionment of data and determination of quota after forfeiture*—(1) *Apportionment of data.* The pounds of farm marketing quota retained on the forfeiting farm after the forfeiture shall be divided by the farm marketing quota established for the farm before the forfeiture to determine a factor for apportioning farm data. The data to be retained on the forfeiting farm shall be determined by multiplying the factor by the following data for the forfeiting farm, the:

(i) Overmarketings which have been subtracted when determining the effective farm marketing quota of the forfeiting farm.

(ii) Pounds of quota transferred from the forfeiting farm by lease or by the owner in the current year.

(iii) Pounds of quota reduced in the current year for a marketing quota violation in a prior year.

(iv) Previous year's effective farm marketing quota.

(v) Previous year's marketings.

(vi) Previous year's farm marketing quota.

(vii) Pounds of quota transferred to the farm by lease or by owner in the previous year.

The portion of the forfeiting farm data which shall be included in a forfeiture pool for the county shall be determined by subtracting the pounds of each respective item of farm data which are retained on the forfeiting farm from the pounds of the respective item of data which were established for the forfeiting farm before forfeiture.

(2) *Forfeiture pool.* The data for the forfeiture pool shall be added to any previous data in the forfeiture pool.

(3) *Quota after forfeiture.* After adjustment of data, the effective farm marketing quota shall be determined in accordance with the provisions of § 723.206 of this part for the forfeiting farm.

(f) *Forfeiture pool*—(1) *Establishing forfeiture pool.* A forfeiture pool shall be established in each county in which a forfeiture of quota occurs. The forfeiture pool shall be increased to include data for each forfeiture and shall be decreased for each reallocation in order to reflect any forfeited or reallocated amounts of the:

(i) Farm marketing quota for the current year.

(ii) Quota reduced for marketing quota violations.

(iii) Quota transferred from the forfeiting farm by lease or by the owner.

(iv) Previous year's effective farm marketing quota.

(v) Previous year's marketings.

(2) *Adjustment of data in forfeiture pool.* At the beginning of the current year, the data in the forfeiture pool shall be adjusted by the factor used in determining quotas for old farms. Quota data in the forfeiture pool shall be decreased each time any burley tobacco quota is reallocated from the forfeiture pool. Such decrease in the quota data will be made in the same proportion as the pounds of quota which are reallocated from the pool are to the pounds of quota which were in the pool before the reallocation.

(g) *Reallocation of quota from forfeiture pool*—(1) *Application.* In order to establish eligibility to receive quota from the forfeiture pool in the current year, an application must be made on a form approved by the Deputy Administrator. Such application must be filed:

(i) *Who may file.* By an active producer.

(ii) *When to file.* On or before April 30. The State ASC committee may establish an earlier date if notice of such earlier date is given in time for interested applicants to file an application by the earlier date.

(iii) *Where to file.* At the county ASCS office which serves the farm for which the application is filed.

(2) *Eligibility of applicant.* In order for an applicant to be eligible for quota from the forfeiture pool, the county ASC committee must determine that:

(i) The application was filed timely.

(ii) The applicant is an active tobacco producer.

(iii) During the current year or during the 4 years preceding the current year, the applicant has not sold or forfeited quota from any farm.

(3) *Time to reallocate.* The county ASC committee shall:

(i) Not reallocate any quota from the forfeiture pool until the time has passed for filing an application for forfeited quota for the current year.

(ii) Reallocate any quota from the forfeiture pool only during the 30-day period beginning on the day after the final day for filing an application for quota from the forfeiture pool.

(4) *Reallocation by county ASC committee.* Reallocation of any burley tobacco quota shall be made by the county ASC committee. In making its determination of the amounts of quota to reallocate, the county ASC committee may consider the size of the current quotas on the farms of the eligible applicants, the length of time the applicants have been farming tobacco, the type of farming done by the applicants (i.e., livestock, grain, or other commodities), previous leasing history of the applicants, and such other factors which in the judgment of the county ASC committee should be considered. A burley tobacco quota may be reallocated to a farm which currently does not have a burley tobacco quota. A factor shall not be used to reallocate quota between all eligible applicants.

(5) *Basis for reallocation from forfeiture pool.* Reallocation from the forfeiture pool shall be on the basis of pounds of farm marketing quota.

(6) *Amount of quota to be reallocated.* The county ASC committee may reallocate all or part of the quota in the forfeiture pool. The minimum amount of quota which may be reallocated to an eligible applicant is the total amount of quota in the pool or 100 pounds, whichever is less. The maximum amount is 500 pounds. However, up to 1,500 pounds may be allocated with State ASC committee concurrence.

(7) *Data for receiving farm.* All data for the forfeiture pool shall be apportioned to the receiving farm in the proportion that the reallocated farm marketing quota is to the total farm marketing quota in the forfeiture pool before the reallocation. The data determined for the receiving farm in accordance with the provisions of this paragraph shall be added to any previous data for the receiving farm.

(8) *Quota for receiving farm.* After any adjustments which are made in accordance with the provisions of this section, the effective farm marketing quota shall be determined for the receiving farm.

(h) *Forfeiture of reallocated quota.* Any burley tobacco quota which is reallocated in accordance with the provisions of this section shall be forfeited if the applicant to whom the quota is reallocated fails to share in the risk of producing a crop of tobacco which is subject to such quota during any of the 5 years beginning with the crop year during which the quota is reallocated. The amount of farm marketing quota which must be forfeited shall be determined in the same manner which is specified in paragraph (c)(4) of this section with respect to the forfeiture of purchased quota. Any forfeiture of quota shall occur on December 1 of the year in which the applicant fails to share in the risk of production of tobacco which is produced subject to such quota. While the failure to utilize a quota shall not subject the quota to forfeiture, the 5-year period which is specified in this paragraph shall be extended by a year for each year in which the allotment and quota is not utilized.

(i) *Successor-in-interest.* A successor-in-interest shall be subject to the provisions of this section in the same manner and to the same extent as would be applicable to the person whose interest has been assumed by such successor-in-interest.

(1) *New owner of farm.* The new owner of a farm on which a portion or all of the farm marketing quota for such farm was either purchased and/or was reallocated from forfeited quota shall become the successor-in-interest to the previous owner of the farm. However, if a farm is acquired by a new owner on or before June 30 of the current crop year and such owner would otherwise be required to sell or forfeit the farm marketing quota because in the preceding crop year the owner of such quota did not share in the risk of producing a crop of tobacco which was subject to such purchased or reallocated quota, the new owner may be considered the buyer of the quota instead of being considered as a successor-in-interest to the previous owner of the farm. However, the new owner must furnish to the county ASC committee on or before June 30 of the current year a certification that such owner intends to become an active burley tobacco producer. Any purchased or reallocated quota, which is acquired by a new owner who is not considered to be the buyer of the quota in accordance with the provisions of this paragraph, shall be subject to the same terms and conditions with respect to forfeiture which would be applicable if the new owner actually had purchased the quota at the time the farm was acquired.

(2) *Buyer no longer shares in risk of production.* The owner of a farm shall become the successor-in-interest to the

buyer of burley tobacco quota which was transferred to a farm but which was not owned by such buyer if the buyer ceases to share in the risk of production of burley tobacco produced on the farm.

§ 723.220 Forfeiture of flue-cured tobacco acreage allotment and marketing quota.

(a) *Determination of allotment and quota subject to forfeiture.* (1) For purposes of paragraphs (b) and (c) of this section, the phrase "owns a farm" means ownership of:

(i) A farm as constituted under part 719 of the chapter if the entire farm shares a common ownership; or

(ii) All of the land within a common ownership if the parent farm consists of separate ownership tracts of land.

(2) For purposes of paragraphs (b) and (c) of this section, the county ASC committee shall, in accordance with the provisions of part 719 of this chapter, apportion the flue-cured tobacco acreage allotment and marketing quota assigned to a farm between:

(i) All land which is owned by any person which is not significantly involved in the management or use of land for agricultural purposes, as described in paragraph (b) of this section; and

(ii) Each common ownership tract of land in the farm other than that described in paragraph (a)(2)(i) of this section.

(3) With respect to the provisions of paragraph (c) of this section, an acreage allotment and marketing quota shall be determined for a tract in accordance with paragraph (a)(2)(ii) of this section only to the extent that records are available to show the contribution which the tract made to the flue-cured tobacco acreage allotment of the parent farm.

(4) The farm acreage allotment and farm marketing quota determined under this section for each farm or tract, as applicable, will be the amount of allotment and quota subject to forfeiture under this section.

(b) *Persons not significantly involved in management or use of land for agricultural purposes.* For purposes of this paragraph, the term "person" means a person as defined in part 719 of this chapter, including any: Governmental entity; public utility; educational institution; or religious institution, but not including any: Individual; partnership; joint venture; family farm corporation; trust, estate, or similar fiduciary account with respect to which 50 percent or more of the beneficial interest is in one or more individuals; or educational institution that uses a flue-cured tobacco acreage allotment and marketing quota for instruction or demonstrational purposes.

(1) *Required forfeiture.* If at any time the county ASC committee determines that any person which owns a farm for which a flue-cured tobacco acreage allotment and marketing quota are established is not significantly involved in the management or use of land for agricultural purposes, such person shall forfeit such allotment and quota which is not sold on or before December 1 of the year for which the county ASC committee makes such a determination.

(2) Owner ceases to be significantly involved. A person shall be considered to be significantly involved in the management or use of land for agricultural purposes if the county ASC committee determines that:

(i) For the 3 preceding years, more than 20 percent of the gross income of the person has been derived from the management or use of land for the production of crops which are planted and harvested annually, and/or livestock, including pasture and forage for livestock; and

(ii) Any other person or all other persons which in combination own more than 50 percent of the assets of the owner of the flue-cured tobacco allotment and marketing quota also meet the criteria specified in paragraph (b)(2)(i) of this section.

(3) *Documentation.* Within 30 days after a written request is made by the county ASC committee, or within such extended time as may be granted by the county ASC committee, a person must submit such documentation as may be requested to support a determination that the provisions of paragraph (b)(2) of this section have been met with respect to such person. Upon failure of such person to timely respond to such request, the county ASC committee shall determine that the person is not significantly involved in the management or use of land for agricultural purposes.

(c) *Flue-cured tobacco farm acreage allotment exceeds 50 percent of tillable cropland.* If any person owns a farm for which the flue-cured tobacco farm acreage allotment assigned to the land owned by the person exceeds 50 percent of the tillable cropland on such farm, the person shall take steps, such as the sale of allotment, the purchase of tillable cropland, or conversion of land to tillable cropland status, which will result in the elimination of the excess or the person shall forfeit flue-cured tobacco farm acreage allotment equal to the amount of such excess that remains on or after:

(1) July 1 of the year, after the year of acquisition, if the farm was acquired after December 1, 1983.

(2) July 1 of the year after the crop year for which the change(s) become effective, for increases in allotment resulting from changes in national acreage or national yield factors.

(3) July 1 of the year after the year in which the farm owner disposes of an acreage of tillable cropland or changes the status of land in the farm so as to cause such land to lose its tillable cropland status.

(d) *Farm includes purchased allotment.* If a farm includes purchased allotment, notwithstanding the provisions of paragraph (c)(1) of this section, when the flue-cured tobacco farm acreage includes acreage of purchased allotment and the flue-cured tobacco farm acreage allotment exceeds 50 percent of the tillable cropland because the owner disposed of an acreage of tillable cropland after purchasing the allotment, the forfeiture shall not take piace until July 1 of the year after the year of such disposal.

(e) *Buyer of allotment fails to share in risk of production*—(1) *Forfeiture required.* If any person buys a flue-cured acreage allotment and quota under the provisions of § 723.216 of this part and such person fails to share in the risk of producing the tobacco which was planted under such allotment and quota during any of the 5-crop years beginning with the crop year for which the purchase became effective, such person shall forfeit the purchased allotment and quota which is not sold on or before December 31 of the year after the crop year in which such crop was planted.

(2) *Fails to utilize purchased allotment and quota.* Failure to utilize purchased allotment and quota for the production of tobacco shall not subject such allotment and quota to forfeiture, but the 5-year period of paragraph (e)(1) of this section shall be extended 1 year for each year in which the allotment and quota is not utilized.

(3) *Reduction for failure to share in risk of production.* The effective allotment and quota shall be reduced, but not below zero acres or pounds, for planting, leasing, and marketing quota purposes only, to the extent of purchased allotment and quota for each crop year after the crop year in which the buyer of such allotment and quota fails to share in the risk of producing a crop of tobacco planted under such allotment and quota.

(4) *Determining forfeited amount.* If only part of the allotment and quota on a farm resulted from purchased allotment or quota, the amount of farm

marketing quota which must be forfeited under paragraph (e) of this section shall be determined by:

(i) Increasing or decreasing each respective purchase of farm marketing quota for the farm to reflect any annual changes in national acreage and national yield factors subsequent to the year of purchase.

(ii) Adding the amounts determined in paragraph (e)(4)(i) of this section, multiplying the result by the farm yield for the farm, and subtracting the pounds of quota which have been sold to prevent forfeiture.

(f) *Tobacco not planted nor considered planted.* Notwithstanding any other provision of this part, any person who owns a farm for which a flue-cured tobacco acreage allotment and marketing quota are established, shall forfeit such allotment and quota after February 15 of any year immediately following the 1st year of the 3-year period immediately preceding the year for which the county ASC committee determines that flue-cured tobacco was not planted nor considered planted on such farm during at least 2 years of such 3-year period.

(g) *Hearing.* Before any forfeiture of allotment and quota becomes effective under the provisions of this section, the county ASC committee shall:

(1) Schedule a hearing for the affected person.

(2) Notify the affected person of the hearing at least 10 days in advance of the hearing.

(3) Make a determination, on the basis of evidence presented at the hearing by or on behalf of the affected person and by or on behalf of the county ASC committee as to whether:

(i) Any of the conditions of requiring forfeiture as specified in this section exist; and

(ii) The affected person knowingly failed to take steps to prevent forfeiture of a flue-cured tobacco acreage allotment and marketing quota.

(4) Notify the affected person of the county ASC committee determination and, if forfeiture of allotment and quota is to be required, afford such person an opportunity to appeal to a review committee under the provision of part 711 of this chapter.

(5) Wait until the period has passed for the affected person to appeal the county ASC committee or review committee determination that allotment and quota must be forfeited under the provisions of this section.

(h) *Apportionment of data and determination of allotment and quota after forfeiture.*—(1) *Apportionment of data.* The pounds of farm marketing quota retained on the forfeiting farm after the forfeiture shall be divided by the farm marketing quota established for the forfeiting farm before the forfeiture to determine a factor for apportioning farm data for the current year and for the base period. The data to be retained on the forfeiting farm shall be determined by multiplying the factor by the following data of the forfeiting farm, the:

(i) Planted and considered planted acres for the base period.

(ii) History acres for the base period.

(iii) Farm acreage allotment for the base period.

(iv) Overmarketings which have not been subtracted when determining the effective farm marketing quota of the forfeiting farm.

(v) Acres of allotment reduced in the current year for a marketing quota violation in a prior year.

(vi) Previous year's effective farm marketing quota.

(vii) Previous year's marketings.

(viii) Previous year's farm marketing quota.

(ix) Pounds of quota transferred from the forfeiting farm by lease in the current year.

(x) Pounds of quota transferred to the farm by lease in the previous year.

The portion of the forfeiting farm data which shall be included in a forfeiture pool for the county shall be determined by subtracting the acres or pounds which are retained on the forfeiting farm from the acres or pounds established for the forfeiting farm before forfeiture.

(2) *Forfeiture pool.* The data for the forfeiture pool shall be added to any previous data in the forfeiture pool.

(3) *Allotment and quota after forfeiture.* After adjustment of data, the effective farm acreage allotment and the effective farm marketing quota shall be determined in accordance with §§ 723.205 and 723.206 of this part, respectively, for the forfeiting farm.

(i) *Forfeiture pool.*—(1) *Establishing forfeiture pool.* A forfeiture pool shall be established in each county in which a forfeiture of allotment and quota occurs. The forfeiture pool shall be increased to include data for each forfeiture and shall be decreased for each reallocation in order to reflect any forfeited or reallocated amounts of the:

(i) Farm acreage allotment for the current year and for the base period.

(ii) Farm marketing quota for the current year and for the base period.

(iii) Acres reduced for violation.

(iv) Planted and considered planted acres for the base period.

(v) History acres for the base period.

(vi) Previous year's effective farm marketing quota.

(vii) Previous year's marketing.

(viii) Quota transferred from the forfeiting farm by lease.

(2) *Yield for forfeiture pool.* The farm yield for the forfeiture pool shall be determined by dividing the farm marketing quota in the forfeiture pool by the farm acreage allotment in the forfeiture pool. The preliminary farm yield for the forfeiture pool shall be determined by dividing the farm yield by the national yield factor.

(3) *Adjustment of data in forfeiture pool.* At the beginning of the current year, the data in the forfeiture pool shall be adjusted by the factors used in determining yields, allotments, and quotas for old farms. Acreage and quota data in the forfeiture poo1 shall be decreased each time quota is reallocated from the forfeiture pool, such decrease to be made in the same proportion as the pounds of quota which are reallocated from the pool are to the pounds of quota which were in the pool before the reallocation.

(j) *Reallocation of allotment and quota from forfeiture pool.*—(1) *Application.* In order to establish eligibility to receive allotment and quota from the forfeiture pool in the current year, an application must be made on a form approved by the Deputy Administrator. Such application must be filed:

(i) *Who may file.* By an active producer.

(ii) *When to file.* On or before March 31. The State ASC committee may establish an earlier date if notice of such earlier date is given in time for interested applicants to file an application by the earlier date.

(iii) *Where to file.* At the county ASCS office which serves the farm for which the application is filed.

(2) *Eligibility of applicant.* In order for an applicant to be eligible for allotment and quota from the forfeiture pool, the county ASC committee must determine that:

(i) The application was filed timely.

(ii) The applicant is an active producer.

(iii) During the current year or during the 4 years preceding the current year, the applicant has not:

(A) Sold or forfeited allotment and quota from any farm.

(B) Used the designation method of division to retain less allotment than the farm would have retained by another method of division.

(3) *Time to reallocate.* The county ASC committee shall:

(i) Not reallocate any allotment and quota from the forfeiture pool until the time has passed for filing an application

for forfeited allotment and quota for the current year.

(ii) Reallocate any allotment and quota from the forfeiture pool only during the 30-day period beginning on the day after the final day for filing an application for allotment and quota from the forfeiture pool.

(4) *Reallocation by county ASC committee.* Reallocation of any allotment and quota shall be made by the county ASC committee. In making its determination of the amounts to reallocate, the county ASC committee may consider the size of the current allotments on the farms of the eligible applicants, the length of time the applicants have been farming tobacco, the type of farming done by the applicants (i.e., livestock, grain, or other commodities), and other factors which in the judgment of the county ASC committee should be considered. Allotment and quota may be reallocated to a farm which currently does not have a flue-cured tobacco allotment. A factor shall not be used to reallocate allotment and quota between all eligible applicants.

(5) *Basis for reallocation from forfeiture pool.* Reallocation from the forfeiture pool shall be on the basis of pounds of farm marketing quota.

(6) *Amount of quota to reallocate.* The county ASC committee may reallocate all or part of the quota in the forfeiture pool.

(i) *Minimum.* The minimum amount of quota which may be reallocated to an eligible applicant is the total amount of quota in the pool or 200 pounds, whichever is less.

(ii) *Maximum.* The maximum amount of quota which may be reallocated to an eligible applicant is 1,000 pounds. However, with State ASC committee approval, up to 2,500 pounds may be allocated.

(7) *Data for receiving farm.* All data for the forfeiture pool shall be apportioned to the receiving farm in the proportion that the reallocated farm marketing quota is to the total farm marketing quota in the forfeiture pool before the reallocation. The pounds of farm marketing quota reallocated to a farm shall be divided by the farm yield for the farm to determine the amount of reallocated farm acreage allotment. The data determined for the receiving farm in accordance with the provisions of this paragraph shall be added to any previous data for the receiving farm.

(8) *Allotment and quota for receiving farm.* After any adjustments which are made in accordance with the provisions of this section, the farm acreage allotment, the effective farm acreage allotment, and the effective farm marketing quota shall be determined for the receiving farm according to §§ 723.205 and 723.206, respectively, of this part.

(k) *Forfeiture of reallocated allotment and quota.* Allotment and quota which is reallocated to a farm under the provisions of this section shall be forfeited if the applicant to whom the allotment and quota is reallocated fails to share in the risk of production of tobacco produced under such allotment and quota during any of the 5 years beginning with the crop year during which the allotment and quota is reallocated. The amount of farm marketing quota which must be forfeited shall be determined in the same manner as is provided in paragraph (e)(4) of this section for forfeiture of purchased quota. Forfeiture shall occur on December 1 of the year in which the applicant fails to share in the risk of production of tobacco which is produced under such allotment and quota. While the failure to utilize such allotment and quota shall not subject such allotment and quota to forfeiture, the 5-year period, as provided for in this paragraph, shall be extended by a year for each year in which the allotment and quota is not utilized.

(l) *Successor-in-interest.* The successor-in-interest shall be subject to the provisions of this section in the same manner and to the same extent as would be applicable to the person whose interest was assumed.

(1) *New owner.* The new owner of a farm on which a portion or all of the farm acreage allotment and farm marketing quota for such farm was either purchased and/or was reallocated from forfeited allotment and quota shall become the successor-in-interest to the previous owner of the farm. However, if a farm is acquired by a new owner on or before June 15 of the current crop year and such owner would otherwise be required to sell or forfeit the farm acreage allotment and farm marketing quota because in the preceding crop year the owner of such allotment and quota did not share in the risk of producing a crop of tobacco which was subject to such purchased or reallocated allotment and quota, the new owner may be considered the buyer of the allotment and quota instead of being considered as a successor-in-interest to the previous owner of the farm. However, the new owner must furnish to the county ASC committee on or before June 15 of the current year a certification that such owner intends to become an active flue-cured tobacco producer. Any purchased or reallocated allotment and quota, which is acquired by a new owner who is considered to be the buyer of the allotment and quota in accordance with the provisions of this paragraph, shall be subject to the same terms and conditions with respect to forfeiture which would be applicable if the new owner actually had purchased the allotment and quota at the time the farm was acquired.

(2) *Buyer no longer shares in risk of production.* The owner of a farm shall become the successor-in-interest to the buyer of allotment and quota which was transferred to a farm but which was not owned by such buyer if the buyer ceases to share in the risk of the production of tobacco produced on the farm.

Subpart C—Tobacco Subject to Quota, Exemptions From Quotas, Marketing Cards, and General Penalty Provisions

§ 723.301 Identification of tobacco subject to quota.

(a) Except as provided in paragraphs (b) and (c) of this section, any tobacco which is determined by a representative of the State ASC committee or county ASC committee to have the same appearance and characteristics as a kind of tobacco for which marketing quotas are in effect shall be deemed to be a quota kind of tobacco. Such tobacco shall continue to be deemed a quota kind of tobacco unless it has been certified by the Agricultural Marketing Service, U.S. Department of Agriculture, under the Tobacco Inspection Act (7 U.S.C. 511) and implementing regulations (7 CFR part 30), prior to removal of the tobacco from the State where it was produced, as a kind of tobacco not subject to marketing quotas.

(b) Any kind of tobacco for which marketing quotas are not in effect that is produced in a State where marketing quotas are in effect for any kind of tobacco shall be subject to the quota for the kind of tobacco for which marketing quotas are in effect in that State. If marketing quotas are in effect in a State for more than one kind of tobacco, nonquota tobacco produced in the State shall be subject to the quota for the kind of quota tobacco produced in the State having the highest price support under the Agricultural Act of 1949.

(c) Paragraph (b) of this section shall not apply to:

(1) Maryland (type 32) tobacco when it is nonquota tobacco and produced on a farm for which a marketing quota for Maryland (type 32) tobacco was established when marketing quotas for such kind of tobacco were last in effect (1965);

(2) Cigar-filler (type 41) tobacco when it is nonquota tobacco and produced in Pennsylvania;

(3) Cigar-wrapper (types 61 and 62) tobacco when it is nonquota tobacco and produced in Connecticut, Massachusetts, Georgia or Florida;

(4) Tobacco produced in a quota State that is represented to be nonquota tobacco and that is readily and distinguishably different from all kinds of quota tobacco, as determined by the Agricultural Marketing Service, U.S. Department of Agriculture, through application of the standards issued by the Secretary for the inspection and identification of tobacco. Such inspection and identification shall be made prior to removal of the tobacco from the State where it was produced; and

(5) Tobacco which is nonquota tobacco and produced in a quota area in which the total of the acreage allotments for quota tobacco established for farms is less than twenty acres.

§ 723.302 Tobacco for experimental purposes.

For farms on which tobacco is being grown for experimental purposes by or under the direction of a publicly owned agricultural experiment station, such tobacco shall be exempt from any penalties otherwise required by this part if, before the beginning of the harvesting of tobacco from any farm on which experimental tobacco is being grown, the director of such publicly owned agricultural experimental station furnishes a report, to the State Executive Director for the State in which the farm is located, that includes the following information:

(a) Name and address of the publicly owned agricultural experiment station.

(b) Name of the owner, and name of the operator if different from the owner, and the farm number of each farm on which tobacco is grown for experimental purposes only.

(c) The acreage of tobacco that is to be grown on each farm for experimental purposes only.

(d) A certification signed by the director of the publicly owned agricultural experiment station to the effect that such acreage of tobacco is being grown for each farm for experimental purposes only, the tobacco is being grown under the auspices of such director, and the acreage of each plot was considered necessary for carrying out the experiment.

§ 723.303 Production of registered or certified flue-cured tobacco seed.

Producers of registered or certified flue-cured tobacco seed may devote flue-cured tobacco acreage in excess of the effective allotment to seed production without such acreage of tobacco causing a "No Price Support" entry on the marketing card issued for the farm if an agreement is signed by the farm operator, and the producer, if different from the operator, which provides:

(a) *Destruction prior to harvest.* For the destruction prior to harvest of all tobacco produced on the acreage designated for seed production.

(b) *Producer payment of compliance costs.* That the producers shall pay the cost of compliance visits to a farm by representatives of the county ASC committee for the purposes of:

(1) Designating and determining the acreage of seed production, and

(2) Determining that no tobacco has been harvested from the acreage designated for seed production and to witness destruction of tobacco leaves.

(c) *Agreement.* That the producer(s) signing the agreement shall agree to timely notify the county ASCS office when the tobacco seed has been harvested.

(d) No history credit. That the planting of the tobacco acreage for seed production will not create history acreage for the purpose of establishing future farm allotments.

(e) *Cancellation of marketing cards.* That if the county ASC committee determines that any of the terms and conditions of the agreement have been violated or any material misrepresentation has been made, any marketing card issued for the farm in recognition of the agreement shall be recalled and canceled, and a marketing card shall be issued to reflect that tobacco produced on the farm is not eligible for price support.

§ 723.304 Determination of discount varieties.

(a) *Definition.* "Discount Variety" means any of the flue-cured tobacco seed varieties designated as Coker 139, Coker 140, Coker 316, Reams 64, Reams 266, or Dixie Bright 244, or a mixture or strain of such seed varieties, or any breeding line of flue-cured tobacco seed varieties, including, but not limited to, 187-Golden Wilt (also designated by such names as No-Name, XYZ, Mortgage Lifter, Super XyZ), having the quality and chemical characteristics of the seed varieties designated as Coker 139, Coker 140, Coker 316, Reams 64, Reams 266, or Dixie Bright 244. However, where there is growing in a field offtype plants of not more than 2 percent, such offtype plants shall not be considered in certifying the flue-cured tobacco variety being produced. Flue-cured tobacco variety which is not certified to be discount variety shall be considered as "acceptable variety."

(b) *Producer report.* The operator, or any producer, on each farm producing flue-cured tobacco shall file with the county ASCS office a report on MQ–32 showing whether or not discount variety tobacco was planted on the farm.

(c) *Failure to file report.* If the operator of a farm on which flue-cured tobacco is being produced in the current year fails or refuses, within 7 days after a request of the county ASC committee on MQ–34–l, Notice of Action Required Regarding Determination of Seed Varieties of Flue-Cured Tobacco, to file a report on MQ-32, showing whether or not there was planted any of the discount varieties of flue-cured tobacco on such farm, all flue-cured tobacco produced on such farm shall be considered by the county ASC committee to be discount variety tobacco unless the county ASC committee finds that failure to comply with the request was due to circumstances beyond the control of the farm operator.

(d) *Notice to farm operator.* The farm operator having discount variety tobacco shall be given written notice by certified mail on MQ–34–2, Notice of Determination of Discount Variety of Flue-Cured Tobacco. This notice to the farm operator shall constitute notice to all persons who, as owner, operator, landlord, tenant, or sharecropper, are interested in the tobacco grown on the farm.

(e) *Producer's right to recertify.* Any producer on a farm who received a Form MQ–34–2 notifying such producer that the farm has discount variety tobacco when in fact an acceptable variety is being produced may recertify on Form MQ–32.

(f) *Issuance of marketing cards*—(1) If a farm is considered to have discount variety tobacco available for marketing and the farm is eligible for price support, the county ASCS executive director shall issue MQ–76, bearing the notation "Discount Variety-Limited Price Support." If the farm is considered to have discount variety tobacco but it is not eligible for price support, the county ASCS executive director shall issue MQ–76, bearing the notation "Discount Variety-No Price Support."

(2)(i) Where an MQ–76, bearing the notation, "Discount Variety-Limited Price Support" is issued for a farm, the card may be exchanged at the county ASCS office for an MQ–76, without the notation, or

(ii) Where an MQ–76, bearing the notation "Discount Variety-No Price Support" is issued for a farm the card may be exchanged at the county ASCS office for MQ–76 with the notation "No

Price Support." However, the farm operator shall establish to the satisfaction of the county ASC committee that there has been no commingling or substitution of discount variety tobacco produced on the farm or on any other farm operated by such operator, and that all discount variety tobacco has been marketed or satisfactorily disposed of, or accounted for.

(3) MQ–76 issued to identify marketings of tobacco grown for experimental purposes by or for publicly owned experiment stations shall bear the notation "Discount Variety-Limited Price Support" if such tobacco is discount variety tobacco.

(g) *Identification of flue-cured leaf account tobacco as acceptable variety*—(1) Whenever the Director determines there is a significant amount of discount variety tobacco available for marketing in any marketing year, the Director may cause to be initiated the provisions of this paragraph. In addition, the Director may terminate any action initiated hereunder when it is determined that no discount variety of flue-cured tobacco remains available for sale during the remainder of the current marketing season. Notification to warehouse operators of action required under this paragraph shall be by the State ASCS executive director.

(2)(i) Each warehouse operator who offers for auction sale any leaf account flue-cured tobacco on a warehouse floor other than such operator's own floor, and who requests the other warehouse operator to identify such tobacco as being "acceptable variety" shall execute MQ–79–1 (Flue-Cured), Dealer's Certification-Resale Tobacco.

(ii) Each warehouse operator who is participating in the Commodity Credit Corporation price support program, and who identifies resale tobacco indicating that such tobacco with a "certified" lot ticket indicating that such tobacco is covered by an executed MQ–79–1.

(iii) Each executed MQ–79–1 (Flue-Cured) shall show the following information with respect to each lot of resale tobacco:

(A) Crop year.

(B) Name and address of warehouse where the tobacco is being offered for sale.

(C) Tobacco sale bill number and date.

(D) Date, signature of dealer and current address, and dealer identification number.

(3)(i) Each dealer or any other person who offers for auction sale any resale flue-cured tobacco on a warehouse floor which is participating in the Commodity Credit Corporation price support program and on which floor eligible resale flue-cured tobacco is identified with a "certified" lot ticket, and who requests the warehouse operator to identify such operator's tobacco as being an "acceptable variety," shall execute MQ–79–1 (Flue-Cured), Dealer's Certification-Resale Tobacco.

(ii) Each executed MQ–79–1 (Flue-Cured) shall show the following information with respect to resale tobacco:

(A) Crop year.

(B) Name and address of warehouse where the tobacco is being offered for sale.

(C) Date, signature of dealer and current address and dealer identification number.

(D) Tobacco sale bill number and date.

(iii) Each dealer or any person who acquires acceptable variety tobacco in a manner which would make it eligible for certification on MQ–79-1, or who has on hand both discount variety tobacco and acceptable variety tobacco, and desires to dispose of acceptable variety tobacco prior to disposing of the discount variety tobacco, may apply in writing to the State ASCS executive director for a special authorization to have the acceptable variety tobacco certified when offered for auction sale.

(h) *Estimate of production.* For any farm on which discount variety tobacco is being grown, a Form MQ–92, Estimate of Production, shall be obtained.

§ 723.305 Issuance of marketing cards.

(a) *General.* Each marketing of tobacco from a farm in a quota area s hall be identified by a valid marketing card unless prior to marketing an AMS certification is issued for such tobacco to indicate that such tobacco is a nonquota kind of tobacco.

(1) A marketing card (MQ–76 or MQ–77) shall be issued for the current marketing year for each farm having quota tobacco available for marketing. Cards shall be issued in the name of the farm operator except that:

(i) Cards issued for tobacco grown for experimental purposes only shall be issued in the name of the experiment station,

(ii) Cards issued to a successor-in-interest shall be issued in the name of the successor-in-interest,

(iii) For kinds of tobacco other than flue-cured and burley, if a part of a farm which includes the tobacco acreage on the farm is cash leased to such producer, cards shall be issued in the name of such producer. The face of the marketing card may show the name of other interested producers. A marketing card may be issued in the name of a producer who is not the farm operator if the county ASC committee determines pursuant to the procedure in paragraph (a)(2) of this section that such producer has been or likely will be deprived of the right to use the marketing card issued for the farm to market such producer's proportionate share of the crop.

(2) If the county ASC committee has reason to believe that one or more producers on the farm have been or likely will be deprived of the right to use such marketing card to market such producer's proportionate share of the crop, a hearing shall be scheduled by the county ASC committee and the operator of the farm and the producer or producers involved shall be invited to be present, or to be represented, at which time they shall be given the opportunity to substantiate their claims concerning the use of the farm marketing card to market each such producer's proportionate share of the effective farm marketing quota for such crop. At least two members of the county ASC committee shall be present at the hearing. The hearing shall be held at the time and place named in the notice. A summary of the evidence presented at the hearing shall be prepared for use of the county ASC committee. If the farm operator or other producer(s) on the farm do not attend the hearing, or are not represented, the county ASC committee shall make its decision on the basis of information available to such committee. If the county ASC committee finds that any producer on the farm has been or likely will be deprived of the right to use the marketing card issued for the farm to market such producer's proportionate share of the crop, a separate marketing card shall be issued to such producer. With respect to burley and flue-cured tobacco, the marketing card issued for the farm shall be recalled and a separate marketing card, showing 103 percent of the producer's proportionate share of the effective farm marketing quota shall be issued to each such producer who it is determined has been or likely will be deprived of the opportunity to market such producer's proportionate share of the crop and another card (or other cards if considered preferable by the county ASC committee) shall be issued showing 103 percent of the effective farm marketing quota to enable the other producers on the farm to market their proportionate shares. The marketing cards issued pursuant to this subparagraph shall reflect the proportionate pounds, if any, already marketed by each producer.

(3) The procedure in paragraph (a)(2) of this section shall not apply to a person who was a producer on the farm in a prior year but who is not a producer in the current crop year.

(b) *Person authorized to issue marketing cards.* The county ASCS executive director shall be responsible for the issuance of marketing cards. For kinds of tobacco other than burley and flue-cured tobacco, each marketing card shall bear the actual or facsimile signature of the county ASCS executive director who issued the card.

(c) *Rights of producers and successors-in-interest.*—(1) Each producer having a share in tobacco available for marketing from a farm shall be entitled to the use of the marketing card for marketing such producer's proportionate share.

(2) Any person who succeeds, other than a dealer, in whole or in part to the share of a producer in the tobacco available for marketing from a farm, shall, to the extent of such succession, have the same right to the use of the marketing card and bear the same liability for penalties as the original producer.

(d) *No price support-burley and flue-cured tobacco.* For burley and flue-cured tobacco, the notation "No Price Support" shall be entered on each marketing card issued for the use of:

(1) *Farm.* The farm if any producer on the farm is ineligible for price support under the provisions of part 1464 of this title.

(2) *Producer.* The producer on a farm if the producer is ineligible for price support under the provisions of part 1464 of this title.

(e) *Farm quota data entered on marketing card and supplemental card for burley or flue-cured tobacco:*

(1) Any marketing card issued to market burley or flue-cured tobacco shall show when issued, in the space provided on the reverse side, the pounds computed by multiplying 103 percent times the effective farm marketing quota.

(2) Notwithstanding paragraph (e)(1) of this section, if the tobacco available for marketing from the farm is determined by the county ASC committee or the county ASCS executive director to be less than the effective farm marketing quota, for purposes of issuing a marketing card and showing thereon the farm's 103 percent of the effective quota, the effective farm marketing quota for the farm shall be considered to be the pounds determined to be available for marketing from the farm. If any producer on the farm satisfies the county ASC committee or county ASCS executive director that the quantity of tobacco produced on the farm in the current year, plus any carryover tobacco from a prior year, is greater than the previously determined pounds of tobacco available for marketing from the farm, the pounds shown on the marketing card shall be increased accordingly, but not to exceed an amount which would cause the total pounds shown on the marketing card to equal 103 percent of the effective farm marketing quota.

(3) Upon request by the farm operator, a supplemental marketing card bearing the same name and identification as shown on the original marketing card may be issued for a farm upon return to the county ASCS office of an original marketing card or a supplemental marketing card. The pounds computed as the balance of 103 percent of quota from a prior marketing card shall be shown in the first space on the reverse side of the marketing card.

(4) Upon written request of the farm operator two or more marketing cards may be issued for a farm if the farm operator specifies the number of pounds of quota to be assigned to each marketing card. In such case, the total pounds of quota specified in the entry, "103 percent of quota," on all marketing cards issued for the farm may not exceed 103 percent of the effective farm marketing quota.

(f) *Farm quota data entered on marketing card and supplemental card for any kind of tobacco other than burley or flue-cured:*

(1) *Within quota marketing card.* A within quota marketing card, MQ–76, indicating the tobacco is eligible for price support shall be issued for use in identifying the kind of tobacco that is available for marketing from a farm when such tobacco:

(i) Is eligible for price support according to the provisions of part 1464 of this title.

(ii) Was grown for experimental purposes by a publicly owned agricultural experiment station.

(2) *Excess marketing card.* An excess marketing card (MQ–77) shall be issued for a farm for marketing a kind of tobacco that is ineligible for price support. Before the MQ–77 is issued the county ASCS executive director shall enter on such marketing card the rate of any penalty that is to be deducted from the proceeds from any marketing of tobacco identified by such marketing card. An MQ–77 shall be issued for each farm for each kind of tobacco for which:

(i) There is excess tobacco available for marketing from the farm; or

(ii) The producer is not an eligible producer or the tobacco is not eligible tobacco as determined in accordance with part 1464 of this title.

(3) *Full penalty rate.* The full penalty rate shall be entered on each MQ 77 issued to identify tobacco produced on a farm for which:

(i) An acreage allotment was not established;

(ii) The farm operator or another producer on the farm prevents the county ASC committee from obtaining information necessary to determine the correct acreage of tobacco on the farm;

(iii) The farm operator fails in accordance with part 718 of this chapter to provide a certification of acreage planted to tobacco, or

(iv) The farm operator or another producer on the farm has not agreed to make contributions to the No Net Cost Fund or pay assessments to the No Net Cost Account, as applicable, in accordance with part 1464 of this title.

(4) *Converted penalty rate.* Except as provided in paragraph (f)(3) of this section, a converted penalty rate shall be entered on each MQ–77 issued to identify tobacco produced on a farm from which there is excess tobacco available for marketing and the percentage of excess is less than 100 percent. For the purpose of determining the penalty due on each marketing by a producer of tobacco subject to penalty, the converted rate of penalty per pound shall be determined by multiplying the applicable rate of penalty for the current crop by the percent excess determined according to this paragraph. For a farm without carryover tobacco from a prior year, the percent excess shall be determined by dividing the excess acreage of tobacco by the harvested acreage of tobacco for the farm. For a farm having carryover tobacco from a prior year, the percent excess shall be determined as follows:

(i) Determine the number of "carryover" acres by dividing the number of pounds of carryover tobacco from the prior year by the normal yield for the farm for that year. Reduce such "carryover" acres by the amount determined by subtracting the harvested acreage from the allotment in the current year. If the "carryover" acres are entirely offset by the underharvested acreage, the percent excess will be zero and a MQ–76 may be issued if the farm otherwise is eligible for price support and the remainder of this paragraph (f)(4) of this section are inapplicable.

(ii) Determine the number of "within quota carryover acres" by multiplying the "carryover acres" by the "percent within quota" (i.e., 100 percent minus the percent excess) for the year in which the carryover tobacco was produced.

(iii) Determine the "total acres" of tobacco by adding the "carryover acres" and the acreage of tobacco harvested in the current year.

(iv) Determine the "excess acres" by subtracting from the "total acres" the sum of the current year's allotment and the "within quota carryover acres."

(v) Determine the percent excess by dividing the "excess acres" by the "total acres."

(5) Except as provided in paragraphs (f) (3) and (4) of this section, a zero penalty rate shall be entered on any MQ–77 issued in accordance with this section.

(g) *Other marketing card data.* Other data specified in instructions issued by the Deputy Administrator shall be entered on the marketing card.

§ 723.306 Claim stamping and replacing marketing cards.

(a) *Claim stamping.* If a person is indebted to the United States and such indebtedness has been recorded on the county debt record, any marketing card issued for the farm on which the person has a producer interest shall bear the notation "U.S. Claim" followed by the amount of the indebtedness. The name of the debtor-producer, if different from the farm operator, shall be recorded directly under the claim notation. The notation "TMQ" indicating tobacco marketing quota as the type of indebtedness shall constitute notice to any buyer that until the amount of penalty is paid, the United States has a lien with respect to any crop of tobacco in which the debtor-producer has an interest. A claim notation other than "TMQ" shall constitute notice to any buyer that subject to prior liens, the net proceeds from any tobacco pledged as collateral for a price support loan shall be paid to the "Agricultural Stabilization and Conservation Service, USDA" to the extent of the indebtedness shown. The acceptance and use of a marketing card bearing a notation and information concerning an indebtedness to the United States shall not constitute a waiver by the debtor-producer of any right to contest the validity of such indebtedness by appropriate appeal. As claim collections are made, the amount of the claim shown on the card shall be revised to show the claim balance. If requested by the producer, the county ASCS executive director who issued the marketing card shall issue a claim-free marketing card when the claim has been paid.

(b) *Replacing, exchanging, or issuing additional marketing cards.* Subject to the approval of the county ASCS executive director, two or more marketing cards may be issued for any farm. Upon the return to the county ASCS office of a marketing card which had been used in its entirety and before the marketing of tobacco from the farm has been completed, a new marketing card bearing the same name, information, and identification as the used card shall be issued for the farm. A new marketing card shall be issued to replace a card which has been determined by the county ASCS executive director who issued the card to have been lost, destroyed, or stolen.

§ 723.307 Invalid cards.

(a) *Reasons for being invalid.* A marketing card shall be invalid if:

(1) If it is not issued or delivered in the manner prescribed;

(2) An entry is omitted or is incorrect;

(3) It is lost, destroyed, stolen, or becomes illegible; or,

(4) Any erasure or alteration has been made and not properly initialed by the county ASCS executive director.

(b) *Validating invalid cards.* If any entry is not made on a marketing card as required, either through omission or incorrect entry, and the proper entry is made and initialed by the county ASCS executive director who issued the card, or by a marketing recorder, then such card shall become valid.

(c) *Returning invalid cards.* In the event any marketing card becomes invalid (other than by loss, destruction or theft, or by omission, alteration, or incorrect entry, which has not been corrected by the county ASCS executive director who issued the card, or by a marketing recorder), the farm operator, or the person in possession of the card, shall return it to the county ASCS office at which it was issued.

§ 723.308 Rate of penalty.

The rate of penalty for a marketing year shall be equal to seventy-five (75) percent of the average market price for the kind of tobacco for the immediately preceding marketing year as determined by the U.S. Department of Agriculture. The rate of penalty will be determined and announced annually for each marketing year in a notice published in the Federal Register.

§ 723.309 Persons to pay penalty.

The persons to pay the penalty due on any marketing of tobacco subject to penalty shall be determined as follows:

(a) *Auction sale.* The penalty due on marketings by a producer or dealer through an auction sale shall be paid by the warehouse operator who may deduct an amount equivalent to the penalty from the price paid to the producer or dealer.

(b) *Nonauction sale.* The penalty due on tobacco acquired directly from a producer or dealer, other than at an auction sale, shall be paid by the person acquiring the tobacco who may deduct an amount equivalent to the penalty from the price paid to the producer or dealer in the case of a sale.

(c) *Marketing outside the United States.* The penalty due on marketings by a producer or dealer directly to any person outside the United States shall be paid by the producer or dealer making the sale.

§ 723.310 Date penalty is due.

(a) *Payment of penalty.* Penalties shall become due at the time the tobacco is marketed, except that in the case of false identification or failure to account for disposition, the penalty shall be due on the date of such false identification or failure to account for disposition. The penalty shall be paid by remitting the amount due to the State ASCS office not later than the end of the calendar week in which the tobacco becomes subject to penalty. A draft, money order, or check drawn payable to the Agricultural Stabilization and Conservation Service may be used to pay any penalty, but any such draft or check shall be received subject to payment at par.

(b) *Auction sale net proceeds.* If the penalty due on any auction sale of tobacco by a producer is in excess of the net proceeds of such sale (gross amount for all lots included in the sale less usual warehouse charges), the amount of the net proceeds accompanied by a copy of the tobacco sale bill covering such sale may be remitted as the full penalty due. Usual warehouse charges shall not include the following:

(1) Advances to producers,

(2) Charges for hauling, or

(3) Any other charges not usually incurred by producers in marketing tobacco through a warehouse.

(c) *Nonauction sales.* Nonauction sales of excess tobacco shall be subject to the full rate of penalty and shall be paid in full even though the penalty may exceed the proceeds for the sale of tobacco.

§ 723.311 Lien for penalty.

(a) *Lien on tobacco.* Until the amount of any penalty which is imposed in accordance with the provisions of section 314 of the Act (7 U.S.C. 1314) is paid, a lien shall exist in favor of the United States for the amount of the penalty on:

(1) The tobacco with respect to which such penalty is incurred; and

(2) Any other tobacco subject to marketing quotas in which the person

liable for payment of the penalty has an interest and which is marketed in the same or a subsequent marketing year.

(b) *Lien precedence.* The lien on any other tobacco attaches at the time the debt is entered on a debt record in:

(1) *Indebted producers.* The county ASCS office for the county in which a subsequent crop of tobacco is grown.

(2) *Indebted warehouse operator.* The State ASCS office for the State in which the warehouse is located.

(3) *Indebted dealer.* The State ASCS office for the State to which the dealer is required to file reports.

(c) *Availability of list of marketing quota penalty debts.* Each county and State ASCS office shall maintain a list of tobacco marketing penalty debts which have been entered on the debt record for the respective office. The list shall be available for examination upon written request by any interested person.

§ 723.312 Request for refund of penalty.

Any person who paid any penalty may request the return of the amount of any such payment which is in excess of the amount required to be paid. Such request shall be filed on Form MQ–85, Farm Record and Account, with the county ASCS office within 2 years after the payment of the penalty. Approval of return shall be by the county ASC committee, subject to the approval of the State ASCS executive director.

§ 723.313 Identification of marketings.

(a) *Burley or flue-cured tobacco.* With respect to:

(1) *Identification of producer marketings.* Each auction and nonauction marketing of burley or flue-cured tobacco shall be identified by a valid marketing card, Form MQ–76, issued for the farm. The reverse side of the marketing card shall show in pounds:

(i) 103 percent of quota,

(ii) Balance of 103 percent of quota after each sale, and

(iii) Date of each sale.

(2) *Cross-references of tobacco sale bill number to prior sale bill.* Each warehouse operator, for each lot of tobacco weighed in on the warehouse floor for sale the same day, shall cross-reference the tobacco sale bill to each prior tobacco sale bill for tobacco identified by the same marketing card. To accomplish the cross-reference, each other tobacco sale bill number shall be entered by the warehouse operator in the "Remarks" space on the tobacco sale bill, on all copies, at the time such tobacco is veighed at the warehouse.

(3) *Recording producer sale.* Each producer sale at auction shall be recorded on Form MQ–72–1, Report of Tobacco Auction Sale, and each producer sale at nonauction shall be recorded on a Form MQ–72–2, Report of Tobacco Nonauction Purchase. For producer sales at nonauction, the dealer purchaser shall execute Form MQ–72–2 and shall enter the data on MQ–76. For producer sales at auction, Form 72–1 and Form MQ–76 shall be executed only by the ASCS marketing recorder.

(4) *Identification of dealer marketings of resale tobacco.* Each auction and nonauction marketing of resale tobacco in the current year, such tobacco shall be identified by a dealer identification card, Form MQ–79–2, issued to the dealer for use in the current marketing year.

(b) *Dark air-cured, fire-cured, or Virginia sun-cured tobacco:* With respect to dark air-cured, fire-cured, or Virginia sun-cured tobacco:

(1) *Identification of producer marketings.* Each marketing of such kind of tobacco from a farm shall be identified by a valid marketing card issued for the farm for the respective kind of a tobacco, either an MQ–76 or MQ–77 (including sale memo). With respect to each nonauction sale from:

(i) A within quota farm a check mark shall be entered on the inside of MQ–76, and

(ii) An excess farm for which an MQ–77 is issued, an executed bill of nonauction sale shall be prepared, and such bill of nonauction sale shall be delivered to a marketing recorder or other person who is authorized to issue sale memos.

(2) *Suspended sale and sales without marketing cards.* Any suspended sale, which is not identified by an MQ–76 or MQ–77 (including a sale memo) on or before the last warehouse sale day of the marketing season, or within 4 weeks after the date of marketing, whichever comes first, shall be identified by MQ–82, Sale Without Marketing Card, as a marketing of excess tobacco. Form MQ–82 shall be executed only by a marketing recorder or other representative of the State ASCS executive director.

(3) *Other persons authorized to execute MQ–76 or MQ–77 (including sale memo).*

(i) A warehouse operator who has been authorized during the current marketing year on MQ–78, Tobacco Warehouse Organization, may record a sale on MQ–76 (or MQ–77, including the issuance of a sale memo) to identify a sale for a farm if a marketing recorder is not available at the warehouse when the marketing card is presented.

(ii) Any warehouse operator, or dealer, who engages in the business of acquiring scrap tobacco from farmers, and who has been authorized on MQ–78, may for each purchase of scrap tobacco execute an MQ–76, or MQ–77 (including a sale memo if the bill of nonauction sale has been executed).

(4) *Verification of sales processed during the absence of marketing recorder.* Any person authorized on MQ–78 to act as a marketing recorder shall promptly present to a marketing recorder for verification each warehouse bill (floor sheet) processed and identified by an MQ–76 or MQ–77 (including any sale memos) executed in the absence of a marketing recorder.

(5) *Withdrawal of approval to act as marketing recorder.* The authorization on MQ–78 for persons may be withdrawn by the State ASCS executive director if such action is determined to be necessary to properly enforce the regulations in this part.

(c) *Separate display on auction warehouse floor.* Any warehouse operator upon whose floor more than one kind of tobacco is offered for sale at public auction shall for each respective kind of tobacco:

(1) Display it in separate areas on the auction warehouse floor.

(2) Use a lot ticket that is distinguishably different from the lot ticket used to identify any other kind of tobacco.

(3) Identify each lot by a lot ticket clearly showing the kind of tobacco. However, if where the tobacco is represented to be a nonquota kind the lot ticket shall have imprinted thereon the type designation for the kind of quota tobacco normally marketed in the area.

(4) Make and keep records that will ensure a separate accounting and reporting of each of such kinds of tobacco (quota and nonquota) sold at auction over the warehouse floor.

(d) *Identification of returned first sale (producer) tobacco.* When resold at auction, tobacco which has been previously sold and returned to the warehouse by the buyer is resale tobacco. When such tobacco is resold by the warehouse operator, it shall be identified as leaf account resale tobacco.

(e) *Verification of penalties by warehouse operators or dealers.* Each sale of tobacco by a producer which is subject to penalty and which has been recorded by a marketing recorder shall be verified by a warehouse operator or dealer to determine whether the amount of penalty shown to be due has been correctly computed. Such warehouse operator shall not be relieved of any liability for the amount of penalty due because of any error which may occur in

computing the penalty and recording the sale.

(f) *Check register.* The serial number of the tobacco sale bill(s) shall be recorded by the warehouse operator on the check register or check stub for the check written covering the auction sale of tobacco by a producer.

(g) *Marketing card and sale memo for cigar tobacco.* With respect to cigar tobacco:

(1) If a sale of producer's cigar tobacco to a buyer is not identified with a marketing card (MQ–76 or MQ–77) issued for the farm, including a sale memo from MQ–77, by the end of the sale day and recorded and reported on MQ–79 (CF&B), Buyers Record, by the tenth day of the calendar month next following the month during which the sale occurred, the marketing shall be identified on MQ–79 (CF&B) as a marketing of excess tobacco and reported not later than the tenth day of the calendar month next following the month during which the sale date occurred, the marketing shall be identified on MQ–79 (CF&B) as a marketing of excess tobacco, and reported not later than the tenth day of the calendar month next following the month during which the sale day occurred.

(2) *Verification of penalty by buyer.* Each excess sale memo issued by a buyer shall be verified by the buyer to determine whether the amount of penalty shown to be due has been correctly computed and such buyer shall not be relieved of any liability with respect to the amount of penalty due because of any error which may occur in issuing the sale memo.

Subpart D—Recordkeeping, reporting requirements, marketing penalties, and other penalties

§ 723.401 Registration of burley or flue-cured warehouse operators or dealers.

(a) *Warehouse registration.* For burley and flue-cured tobacco, any warehouse operator dealing in either flue-cured or burley tobacco shall be registered with the U.S. Department of Agriculture. Such registration will be handled by the North Carolina State ASCS Office, Raleigh, North Carolina.

(b) *Dealer registration.* Except for dealers who are exempt from the requirements for maintaining regular records and reports on the Form MQ–79 as provided in § 723.405 of this part, each person who expects to deal in burley and flue-cured tobacco during a marketing year shall annually register with the U.S. Department of Agriculture for the respective marketing year beginning with the 1989–1990 marketing year. Such registration shall be handled by the North Carolina State ASCS Office, Raleigh, N.C. Registration may be accomplished by such person filing a MQ–79–2–A, after March 1 of the calendar year in which the marketing year begins, at the local county ASCS office where the applicant resides or where the applicant's principal business is located. The applicant shall provide the names of other individuals who will be authorized to use the assigned dealer registration number to transact business on behalf of the applicant. Only one dealer registration number will be issued to each dealer entity. Persons maintaining the same residence shall be considered one entity, unless such persons can substantiate to the satisfaction of the State ASC committee for the State in which the application is made, that such persons operate their tobacco business entirely as separate entities.

(1) *Issuance of dealer cards.* After approval by the North Carolina State ASCS Office, each dealer will be assigned a four-digit identification number and issued a dealer identification card (Form MQ–79–2).

(2) *TMQ lien notation.* If a claim has been established against a dealer as a result of a tobacco marketing quota penalty such dealer, upon notification by the applicable State ASCS office, shall return the dealer identification card to the State ASCS office within 15 days of notification. Upon timely return of the dealer identification card the claim shall be annotated on the card and promptly returned to the dealer.

§ 723.402 Warehouse authorized to retain producer marketing cards between sales.

(a) *General.* Notwithstanding any other provisions of this part, to facilitate the scheduling of farmer's tobacco to the warehouse, marketing cards with the permission of the producer may be retained at the warehouse between sales even though no producer on the farm for which the card is issued has tobacco on the floor for sale or to be settled for, as provided in this section.

(b) *Warehouse eligible to retain producers marketing cards between sales.* A warehouse shall be eligible to retain producer marketing cards between sales if the operator thereof shall:

(1) Execute and file on a form approved by ASCS a written request with the State ASC committee (or county ASC committee if designated by the State ASC committee).

(2) Agree to be responsible to ASCS for an amount of money equal to the amount that may be assessed against any producer as marketing quota penalties, if the marketing that is the basis of assessment of penalty occurred while the warehouse was authorized to have custody of the marketing card, for:

(i) Burley or flue-cured tobacco for any overmarketing resulting from errors made at the warehouse in entering "balance after sale" pounds on the producer's marketing card or failure to deduct pounds sold on producer's marketing card.

(ii) Tobacco falsely identified for marketing by use of the producer's marketing card.

(iii) Producer's failure to account for any tobacco marketed by use of the producer's marketing card.

(iv) Any burley or flue-cured tobacco marketed at the warehouse in excess of 103 percent of quota as shown on the producer's marketing card.

(3) Agree to maintain an accurate and up-to-date journal containing a listing of all producer marketing cards retained by the warehouse to facilitate the scheduling of farmer's tobacco. The journal shall show for each card retained the:

(i) Name of the operator;

(ii) Serial number of farm;

(iii) Marketing card number, if applicable;

(iv) Date marketing card obtained from producer; and

(v) Date marketing card returned to producer.

Such journals shall be maintained for the length of time and under the conditions required for other warehouse records.

(4) Agree to return the marketing card to the producer at any time the producer may so request, or in the absence of a request, return it to the producer within 7 days after the close of the warehouse for the season.

(5) Agree that this authorization may be terminated by ASCS for failure to comply with provisions of this agreement.

(c) *Penalties considered to be the responsibility of warehouse operators.* Notwithstanding any other provision of this part, a warehouse operator who executes and files a written request with the State ASC committee (or county ASC committee if designated by the State ASC committee) for authorization to retain producer's marketing cards at the warehouse, with grower permission, shall be responsible to ASCS for an amount of money equal to the amount that may be assessed against the producer as marketing quota penalties if the marketing that is the basis of such assessment occurred while the warehouse was authorized to have custody of the marketing card, for:

(1) Any burley or flue-cured tobacco overmarketings resulting from errors made at the warehouse in entering "balance after sale" pounds on the burley or flue-cured producer's marketing card or failure to deduct pounds sold on the producer's marketing card. However, the warehouse operator shall not be responsible for any penalty under this subparagraph, if such penalty would not have been assessed against the producer in accordance with § 723.409(e) of this part.

(2) Tobacco falsely identified for marketing by use of the producer's marketing card.

(3) Producer's failure to account for any tobacco marketed by use of such producer's marketing card.

(4) With respect to burley or flue-cured producers, tobacco marketed at the warehouse in excess of 103 percent of quota as shown on the producer's marketing card.

§ 723.403 Auction Warehouse operators' records and reports.

(a) *Report on Form MQ–78, Tobacco Warehouse organization.* Each warehouse operator shall annually, prior to opening of auction markets, furnish ASCS an executed Form MQ–78 showing:

(1) Form of business organization.

(2) Names and addresses of warehouse officials and bookkeeper.

(3) Names and addresses of other warehouses in which the officials and bookkeepers have a financial interest.

(4) Names and address of custodian of warehouse records, including their location.

(b) *Separate records and reports.* Each auction warehouse operator shall keep the records and make the reports separately for each quota or nonquota kind of tobacco as provided in this section.

(c) *Record of marketing.* Each warehouse operator shall:

(l) *Auction or nonauction sale.* Keep such records as will enable the warehouse operator to furnish the following information to State ASCS office with respect to each sale of tobacco made at such person's warehouse:

(i) The name of the operator of the farm on which the tobacco was produced and the name of the producer, in the case of a sale by a producer.

(ii) The name of the seller in the case of a resale.

(iii) Date of sale.

(iv) Number of pounds sold.

(v) Amount of any penalty and the amount of any deduction for such penalty from the price paid the producer.

(vi) With respect to each individual lot of tobacco constituting an auction sale, the:

(A) Name of purchaser.

(B) Number of pounds sold.

(C) Gross sale price.

(2) *Separate account records.* Maintain records of all purchases and resales of tobacco by the warehouse operator to show a separate account for:

(i) Nonauction purchases by or on behalf of the warehouse operator of farmer owned tobacco.

(ii) Purchases and resales of:

(A) Leaf account tobacco.

(B) Floor sweeping tobacco.

(d) *Tobacco sale bill for burley and flue-cured tobacco.* (1) Each burley or flue-cured tobacco warehouse operator shall use tobacco sales bills furnished at the warehouse operator's expense showing, as a minimum, the following information:

(i) Tobacco sale bill number;

(ii) For flue-cured tobacco only, registration number assigned the warehouse by the Department;

(iii) Name and address of warehouse where sale is held;

(iv) For flue-cured tobacco only, the identification of other producers having an interest in the tobacco;

(v) Date of sale;

(vi) Number of pounds in each lot;

(vii) Name and address of seller; and

(A) Farm number (including State and county codes) for producer tobacco, and

(B) Dealer registration number for resale tobacco;

(viii) Identification number, if available, for each lot of tobacco to be offered for sale;

(ix) Poundage balance before sale for producer tobacco based on 103 percent of farm quota;

(x) Name or symbol of purchaser of each lot which is sold;

(xi) Gross number of pounds sold;

(xii) Sales price for each lot and gross sale price for all lots sold;

(xiii) Nonauction purchases by the warehouse holding the sale;

(xiv) Tobacco grade for tobacco consigned to price support;

(xv) The buyer's grade symbol for tobacco bought by private buyers.

(xvi) The letters "N/A" in the buyer and grade space for nonauction purchases by the warehouse.

(xvii) Marketing quota penalty collected; and

(xviii) Amount withheld from sale to cover claims due the United States.

(2) At the end of each sale day, the tobacco sale bills shall be sorted and filed in numerical order by sale dates, and lot tickets shall be filed in an orderly manner by sale dates or by numerical order.

(e) *Identification of tobacco for marketing*—(1) *Marketing card.* Each marketing of tobacco from a farm in any State for which a farm marketing quota has been established for any kind of tobacco shall be identified by a marketing card issued for the farm on which such tobacco was produced (unless prior to the marketing of such tobacco an AMS inspection certificate is obtained showing that the tobacco offered for sale is a kind of tobacco not subject to marketing quotas).

(2) *Recording farm identification.* For burley or flue-cured tobacco, at the time the tobacco is weighed in, the warehouse operator shall record on the tobacco sale bill, the State and county codes and the farm serial number from the marketing card issued for the farm from which the tobacco is to be marketed.

(3) *Return of marketing card.* For tobacco that is to be sold at auction, the warehouse operator shall retain the marketing card until the producer has been paid for the sale of the tobacco or the tobacco is removed from the warehouse by the producer at which time the marketing card shall be returned to the producer. In any case where a producer's marketing card is found in the possession of a warehouse operator, and no producer on the farm for which the card is issued has tobacco on the floor for sale, or tobacco for which settlement is not yet completed, such card will be picked up by an ASCS representative for return to the producer. The warehouse operator shall be responsible for the safekeeping and proper use of the marketing card during such person's retention of the marketing card.

(4) *No price support.* For burley or flue-cured tobacco, if tobacco is to be marketed at auction from a farm for which a marketing card is issued bearing the notation "No Price Support", the warehouse operator shall enter the same notation on the tobacco sale bill at the time the tobacco is weighed in for sale. The warehouse operator shall prepare a separate tobacco sale bill to cover any tobacco which represents more than 103 percent of the effective farm marketing quota and the notation "No Price Support" shall be shown on such tobacco sale bill. The sale of such tobacco shall be considered a separate sale.

(5) *Nonauction purchase.* The warehouse operator shall enter the letters "NA" on each line of a tobacco sale bill on which there is recorded tobacco purchased by or for the warehouse at nonauction sale and shall record on all such tobacco sale bills:

(i) For burley or flue-cured tobacco, the farm serial number from the marketing card that is used to identify the tobacco at the time of the nonauction purchase.

(ii) For tobacco other than burley or flue-cured, the serial number of the marketing card that is used to identify the tobacco at the time of the nonauction purchase.

(6) *Copy of sale bill.* The warehouse operator shall furnish to the producer a copy of the tobacco sale bill bearing the letters "NA" for any lot of such tobacco purchased by the warehouse operator.

(7) *Basket ticket.* At the time tobacco is weighed for marketing, the warehouse operator shall record the weight of the lot of tobacco on the tobacco sale bill and on the lot ticket. The sale bill number on which the lot of tobacco is recorded shall be recorded on the lot ticket. If the marketing card which is presented to identify the tobacco at weigh-in bears the notation "No Price Support," the same notation shall be entered by the warehouse operator on the lot ticket for each lot of tobacco which is identified with the same marketing card.

(8) *Recording serial number of marketing card.* For tobacco other than burley or flue-cured, before the tobacco is offered for sale, the warehouse operator shall record, on the sale bill, the serial number of the Form MQ–76 or MQ–77 issued for the farm from which the tobacco is to be marketed at auction.

(9) *Recording sale bill number.* For tobacco other than burley or flue-cured, the serial number of the sale bill shall be recorded:

(i) By the warehouse operator on the check register or check stub from the check written to cover an auction sale of tobacco by a producer.

(ii) On the inside of the marketing card by the marketing recorder or warehouse operator for each sale of tobacco by a producer.

(10) *Burley or flue-cured marketings.* A marketing card used to cover a sale of burley or flue-cured tobacco shall show on the reverse side the poundage balance of the "103 percent of quota."

(i) *Auction sale.* At the time of weigh-in the tobacco sale bill shall show the poundage balance of 103 percent of the farm's quota. The tobacco sale bill shall show the pounds on which penalty is due, and the amount of penalty.

(ii) *Nonauction sale to a warehouse operator at the warehouse.* If the tobacco sale bill includes both an auction sale and a nonauction sale such combined pounds shall be used to compute and reflect the balance of the "103 percent of quota." The tobacco sale bill shall show the pounds on which penalty is due and the amount of the penalty.

(iii) *Nonauction country purchase by a warehouse operator.* The warehouse operator shall deduct, from the balance of the "103 percent of quota" entry on the marketing card, the pounds of tobacco purchased as a nonauction country purchase. In addition, each warehouse operator shall record on Form MQ–79 and on Form MQ–72–2, Report of Tobacco Nonauction Purchase, each nonauction country purchase of tobacco made by such warehouse operator. The data to be reported on Form MQ–72–2 is set forth in § 723.404 of this part.

(11) *Sale memo and bill of nonauction sales.* For tobacco other than burley or flue-cured, a record of sales on Forms MQ–76, MQ–77, or MQ–82, Sale Without Narketing Card (including sale memo from MQ–77 or MQ–82), shall be obtained by a warehouse operator to cover each marketing of tobacco from a farm through a warehouse and each nonauction sale of tobacco purchased by or for the warehouse operator including scrap tobacco obtained as result of providing curing space or stripping space for farmers. Each MQ–76 and MQ–77 (including sale memo) shall be executed as follows:

(i) *Auction sale.* An auction sale identified by MQ–76 shall show in the spaces provided therefor, the sale bill number, check-mark to show the sale was by auction, a check-mark to show nonauction for purchases identified "NA" on the sale bill, pounds sold, name and address of warehouse, and date of sale. In addition, each sale memo issued from MQ–77 to cover an auction sale shall show on the first page thereof in all of the spaces provided therefor, the warehouse bill number, pounds sold, amount of penalty due, name and address of warehouse, and date of sale.

(ii) *Nonauction sale to a warehouse operator who does not prepare a sale bill.* An MQ–76 used to cover a nonauction sale of tobacco to a warehouse operator who does not prepare a sale bill to cover the sale shall show, a check-mark to indicate sale was by nonauction, pounds sold, name and address of the warehouse, and date of sale. When an MQ–77 is used under this paragraph, a sale memo shall be executed, including the signature of the producer on the reverse side.

(iii) *Nonauction sale to a warehouse operator who prepares a sale bill.* When a warehouse operator purchases:

(A) All the delivery of a producer's tobacco at a nonauction sale and prepares a sale bill to cover the purchase, on MQ–76 there shall be shown the bill number, check-mark to show nonauction purchases, pounds sold, name and address of warehouse, and date of sale. When an MQ–77 is used a sale memo shall be executed, including the signature of the producer on the reverse side.

(B) Part of a delivery of a producer's tobacco as a nonauction purchase and the remainder of the tobacco is sold at auction, if such tobacco is identified by an MQ–76 the Record of Sales shall be completed to show the name and address of the warehouse, the date of sale, the sale bill number, check-mark under both auction and nonauction, and, under "Lbs. Sold," the total number of pounds covered by the entire delivery. If the sale is identified by an MQ–77, the sale memo (front) shall be completed to show the sale bill number, the total number of pounds covered by the entire delivery under "Lbs. Sold," the amount of penalty due, name and address of the warehouse, and the date of sale. In addition the reverse side of the sale memo shall show the number of pounds sold at nonauction.

(f) *Nonquota tobacco or quota tobacco of a different kind.* If tobacco is presented for sale that is represented to be nonquota tobacco or should there be a question as to what kind of quota tobacco is being offered for sale, an inspection shall be obtained from the Agricultural Marketing Service of this Department (AMS) after the tobacco is weighed and in line for sale. The lot ticket for the tobacco shall be cross-referenced to the sale bill by sale bill number and date. The sale bill shall show the producer's name and address and the State and county code and farm number of the farm on which the tobacco was produced. If an AMS inspection shows that a lot of tobacco is of a different kind than that identified by the lot ticket, such tobacco shall be deleted from the original sale bill and a revised sale bill prepared. Copies of the lot ticket and sale bill shall be furnished to the State ASCS office at the end of the sale day.

(g) *Labeling tobacco sale bill for resale tobacco.* In the case of resales, each sale bill shall show "resale" and:

(1) For dealers, the name of the dealer making each resale; and

(2) For the warehouse, the name of the warehouse and either "floor sweepings" or "leaf account" tobacco.

(h) *Suspended sale record.* (1) Any tobacco sale bill covering sale of tobacco for which a valid marketing card or dealer identification card was not presented at the end of the sale day shall be given to a marketing recorder who shall stamp such bills, "Suspended", and shall handle

according to instructions provided by the Deputy Administrator.

(2) When cleared, such suspended sale shall show "suspended-cleared" and date cleared. If a suspended sale is not cleared from suspension by the last auction sale day for the warehouse for the season, (or for burley tobacco only, within 7 days of the sale if such date is earlier) it shall be considered a sale of excess tobacco and penalty at the full rate shall be remitted by the warehouse operator.

(i) *Payee to be shown on auction warehouse check.* Any auction warehouse which issues a check to cover the auction or nonauction sale of tobacco shall issue such check only in the name of the payee. A warehouse check shall not be issued in the name of the seller and bearer, for example "John Doe or Bearer."

(j) *Warehouse entries on other dealer's reports.* Each warehouse operator shall record, or have the dealer record, on a Form MQ–79 the total purchases and resales made by each such dealer or other warehouse operator during each sale day at the warehouse. Warehouse operators shall sign the Form MQ–79 on the same line as the transaction is recorded when a dealer resells tobacco at the warehouse. If any tobacco resold by the dealer and carried over by the dealer from a crop produced prior to the current crop, an entry shall be made on the MQ–79 to clearly show such fact.

(k) *Warehouse data for burley or flue-cured tobacco.* (1) Each operator of a burley or flue–cured tobacco auction warehouse shall prepare at the end of each sale day a report on MQ–80, Daily Warehouse Sales Summary, showing for each sale day:

(i) For each manufacturer, buyer, order buyer, and any tobacco cooperative, pounds of tobacco purchased at auction, (consigned in the case of tobacco cooperatives).

(ii) The sum of the items for paragraph (k)(1)(i) of this section.

(iii) Resales at auction for each person listed under paragraph (k)(1)(i) of this section.

(iv) For each dealer subject to reporting purchases and resales on MQ–79, as originally billed, the total pounds of tobacco purchased at auction, and resales at auction.

(v) The total pounds purchased at auction at the warehouse for the leaf account.

(vi) The total pounds purchased at nonauction at the warehouse for the leaf account.

(vii) The sum of the total pounds for paragraphs (k)(v) and (vi) of this section.

(viii) The total leaf account resales.

(ix) The total floor sweeping resales.

(x) The sum of the total purchases for paragraphs (k)(1)(ii), (iv), and (vii) of this section.

(xi) The sum of the total resales for paragraphs (k)(1)(ii), (iv), (viii) and (ix) of this section.

(xii) The totals of the purchases column on the Form MQ–79 representing the nonauction purchases for the warehouse leaf account.

(xiii) The totals of the resales column on Form MQ–79 representing the nonauction resales (including floor sweepings nonauction sales) by the warehouse.

(xiv) For each warehouse sale of excess tobacco from a farm, the applicable farm number with daily remittance of the penalty due to accompany Form MQ–72–1.

(xv) For each dealer, at the time of settlement having excess resale tobacco, the applicable dealer identification number with daily remittance of the penalty due.

(2) As to the information required to be entered on MQ–80, Daily Warehouse Sales Summary, by the marketing recorder, the warehouse operator shall keep and make available such records as will enable the marketing recorder to enter thereon:

(i) The total number of Forms MQ–72–1 for the sale day and the sum of pounds sold, and

(ii) The total number of suspended sale bills and the sum of such pounds sold.

(3) At the end of the season, each warehouse operator shall:

(i) Report on the final MQ–80 for the season the quantity of leaf account tobacco and floor sweepings, if any, on hand and its location,

(ii) Permit its inspection by a representative of ASCS, and

(iii) Provide for the weighing of such tobacco, to be witnessed by an ASCS representative, and furnish to such representative a certification as to the actual weight of such tobacco. After the weight of such tobacco has been obtained, it shall be considered as the official weight for comparing purchases and resales for the purpose of determining the amount of penalty, if penalty is due.

(4) The warehouse operator shall furnish to the marketing recorder a copy of each executed MQ–80.

(5) Before the next marketing season begins, carryover tobacco reported by the warehouse operator as provided in paragraph (k)(3) of this section shall be reinspected by a representative of ASCS.

(i) If the reinspection indicates an amount of carryover tobacco different from that amount determined by the initial inspection, the warehouse operator shall:

(A) Provide for the weighing of such tobacco which shall be witnessed by a representative of ASCS.

(B) Furnish to such representative at the time of weighing a certification as to the actual weight of the tobacco.

(ii) If the ASCS representative determines that the weight of the tobacco is different, by reweighing, than the amount reported on the initial certification, the initial weight, together with the reweighed quantity after taking into consideration any purchases and resales that occurred subsequent to the initial certification as provided in paragraph (k)(3) of this section, shall be used for the purpose of determining the amount of penalty, if penalty is due.

(iii) The reweighed quantity shall be the official pounds to be credited to the account as carryover tobacco.

(l) *Warehouse data for tobacco other than burley or flue-cured.* (1) Each operator of a tobacco auction warehouse, other than the operator of a burley or flue-cured auction warehouse, shall prepare and promptly forward at the end of each sale day to the State ASCS office a report on MQ–80, Daily Auction Warehouse Report, showing for each sale day, unless otherwise stated below:

(i) For each dealer or buyer as originally billed, the total pounds of tobacco purchased at auction and resales at auction on the warehouse floor.

(ii) For any association as originally billed, the total pounds and gross amount of loan tobacco acquired at auction, and resales at auction, if any, on the warehouse floor.

(iii) The total pounds of:

(A) Leaf account purchases at auction on the warehouse operator's own floor,

(B) Leaf account purchases at nonauction sale for which a floor sheet is prepared,

(C) All leaf account resales at auction on the warehouse operator's own floor, including resales of tobacco from the warehouse operator's buyers corrections account, and

(D) All resales at auction on the warehouse operator's own floor of floor sweepings which accumulated on the warehouse operator's own floor.

(iv) The respective sums of the purchases, including loan tobacco, and resales for paragraphs (l)(1) (i), (ii), and (iii) of this section.

(v) The computed total of first sales at auction on the warehouse floor.

(vi) The warehouse gross sale pounds for the day as billed to buyers.

(vii) The pounds on warehouse check register if shown thereon, and

(viii) The total pounds of the resales.

(ix) On the report for the last sale day for the season, the pounds of all tobacco on hand whether such tobacco represents leaf account tobacco or floor sweepings which accumulated on the warehouse operator's own floor.

(x) For each warehouse sale of excess tobacco from a farm, the applicable sale memo and numbers thereof with remittance of the penalty due as shown thereon.

(2) As to information required to be entered on MQ–80, Daily Auction Warehouse Report, by the marketing recorder, the warehouse operator shall keep and make available such records as will enable the marketing recorder to enter thereon:

(i) For each sale identified by an MQ–76, MQ–77 (including sale memo), or MQ–82, Sale Without Marketing Card, the pounds sold;

(ii) For each sale suspended, the warehouse bill(s) number and pounds sold;

(iii) For each sale cleared from suspension, the MQ–76 number or, for MQ–77 or MQ–82, the sale memo number and the date of clearance.

(3) When a producer rejects the sale of a lot of tobacco, and the tobacco has been billed out and the bills presented to the buyer, the warehouse operator shall not change the marketing card, or Form MQ–80 on which the sale was reported. If the warehouse operator gains possession of the tobacco and it is resold by such warehouse operator, it shall be identified as resale tobacco.

(4) In balancing first sales (represented by marketing recorder's total) with computed first sales (bill-out total minus resales as reported by the warehouse operator) the State ASCS executive director is authorized to approve reports with variance not to exceed one-half of 1 percent of such pounds.

(5) At the end of the season, each warehouse operator shall:

(i) Report on the final MQ–80 for the season the quantity of leaf account tobacco and floor sweepings, if any, on hand and its location,

(ii) Permit its inspection by a representative of ASCS, and

(iii) Provide for the weighing of such tobacco (to be witnessed by a representative of ASCS) and furnish to such representative a certification as to the actual weight of such tobacco. After the weight of such tobacco has been obtained, it shall be considered as the official weight for comparing purchases and resales for the purpose of determining the amount of penalty, if penalty is due. Separate data shall be reported for floor sweeping tobacco.

(m) *Bill-out invoice.* For flue-cured tobacco when the tobacco has been sold at auction, the bill-out invoice to the buyer shall include the warehouse registration number (warehouse code), sale bill number, and line number on which the lot of tobacco was recorded on the sale bill.

(n) *Maintaining copies of bill-out invoices to purchaser or daily summary journal sheet to reflect daily transactions.* For each marketing year, the warehouse operator shall maintain copies of the bill-out invoice to the purchaser by grades showing the pounds purchased. In lieu of this requirement, the warehouse operator may prepare and maintain for each sale day on a current basis a daily summary journal sheet to reflect for each purchaser (including warehouse leaf account or other similar account) pounds and dollar amounts for:

(1) Tobacco originally billed to the purchaser.

(2) Mathematical billing errors and corrections (added and deducted) from purchaser's adjustment invoices.

(3) Short (deducted) and long (added) weights from purchaser's adjustment invoices.

(4) Short (deducted) and long (added) lots from purchaser's adjustment invoices.

(5) Net tobacco received and paid for by purchase.

(o) *Handling rejected (producer) sale after bill-out.* Where a producer rejects the sale of a lot of tobacco, and the tobacco has been billed-out and bills presented to the buyer, the warehouse operator shall not change the MQ–76 or MQ–80 on which the sale was reported. If the warehouse operator gains possession of the tobacco, and it is resold by such warehouse operator, it shall be identified as resale tobacco.

(p) *Report to county ASCS office of long weights and long lots.* Each warehouse operator shall report to the county ASCS office or maketing recorder long weights and long lots of producer tobacco (first sales) for which the farmer has been paid.

(q) *Record and report of warehouse operator's leaf account purchases and resales not on such warehouse operator's floor.*

(1) Each warehouse operator shall keep a record and make reports on MQ–79, Dealer's Report, showing:

(i) All nonauction purchases of tobacco, except nonauction purchases at such warehouse operator's warehouse which are reported on MQ–80.

(ii) All purchases and resales of tobacco at public auction through warehouses other than such operator's own warehouse.

(iii) All nonauction resales of tobacco.

(2) Form MQ–79 shall be prepared and a copy, including copies of Form MQ–72–2 for all nonauction purchases of burley or flue-cured tobacco, forwarded to the State ASCS office not later than the end of the calendar week (at the end of each sale day during the auction season for such warehouse) in which such tobacco was purchased or resold.

(3) If tobacco is purchased prior to the opening of the local auction market, an MQ–79 shall be prepared and a copy, together with copies of MQ–72–2 for all nonauction purchases of burley or flue-cured tobacco, forwarded to the State ASCS office not later than the end of the calendar week which would include the first sale day of the local auction markets.

(4) A remittance for all penalties shown by the entries on Form MQ–79 and Form MQ–72–2 to be due shall be forwarded to the State ASCS office with the original copy of MQ–79.

(5) Resales of floor sweepings shall be reported separately from leaf account tobacco.

(r) *Buyers corrections account.* Each warehouse operator shall keep such records including negative adjustment invoices as will enable the warehouse operator to furnish a weekly report on Form MQ–71 to the State ASCS office showing the total pounds of the debits (for returned lots, short lots, and short weights of tobacco) and the credits (for long lots and long weights of tobacco) to the buyers corrections account. Where the warehouse operator returns to the seller tobacco debited to the buyers corrections account, the warehouse operator shall prepare an adjustment invoice to the seller. This invoice shall be the basis for a credit entry for the warehouse in the buyers corrections account and a corresponding purchase (debit entry) in the case of a dealer on such dealer's MQ–79, Dealer's Report. Any balancing figure reflected on the warehouse operator's summary of bill-outs shall not be included in the buyers corrections account.

(s) *Reporting of processed leaf account tobacco.* Any warehouse operator who delivers tobacco to a firm for the purpose of redrying, processing, or stemming of such tobacco shall, by the end of the week in which such tobacco was delivered, report to the State ASCS office on MQ–79, Dealer's Report:

(1) The date delivered;

(2) Name and address of the firm to which the tobacco was delivered, and

(3) The pounds of tobacco (green weight) delivered which shall be entered in the resales pounds column. Such tobacco shall be considered a resale on the date of delivery for the purpose of balancing the warehouse account and collection of penalties where penalties are due.

(t) *Report of farm scrap resulting from grading tobacco for farmers.* Any warehouse operator or any other person who grades tobacco for farmers shall maintain records which will enable such person to furnish the State ASCS office the name of the farm operator and the approximate amount of scrap tobacco obtained from the grading of tobacco from each farm.

(u) *Report of farm scrap resulting from furnishing stripping space for farmers.* Any warehouse operator or any other person who provides tobacco curing space or stripping space for farmers shall maintain records which will enable such person to furnish the State ASCS office the name of the farm operator and the approximate amount of scrap tobacco obtained from each farm resulting from providing such space.

(v) *Producer tobacco.* Producer tobacco (first sale) in possession of a warehouse operator, resulting from long weights and long lots, which has not previously been identified by a sale shall be recorded and reported in the same manner as a nonauction sale to a warehouse operator who does not prepare a warehouse bill (floor sheet) and shall be reported on MQ–79, Dealer's Record. Penalty shall be due on this tobacco at the full penalty rate for the respective kind of tobacco or, if the kind is not known, at the penalty rate for the kind of tobacco generally marketed through the warehouse.

§ 723.404 Dealer's records and reports, excluding cigar tobacco buyers.

(a) *General.* This section is applicable to all kinds of tobacco except cigar tobacco.

(1) Each dealer, except as provided in § 723.405 of this part shall keep by kinds of tobacco the records and make the reports separately for each kind (quota and nonquota) of tobacco as provided in this section. Adjustment invoices, including the adjustment invoices for any sale day for which there is no adjustment to be made, required to be furnished to an auction warehouse shall be identified by the warehouse identification number (if applicable) and the reporting dealer's identification number (if applicable) as well as the names of the warehouse and dealers involved in the transaction.

(2) Each dealer shall properly execute the "Receipt for Dealer's Record" contained in MQ–79, which is issued to the dealer, and shall transmit such receipt to the applicable State ASCS office.

(b) *Record of marketings.* A dealer shall keep records which provide the following information for each lot of tobacco, including scrap tobacco, purchased or sold by the dealer:

(1) *Purchases.* (i) The name of:

(A) The warehouse through which the tobacco was purchased, if purchased at a warehouse auction; or

(B) The operator of the farm on which the tobacco was produced, if purchased from a producer as a nonauction purchase, and the name of the producer of the tobacco, if different from the operator; or

(C) The seller if purchased as a nonauction purchase from a warehouse operator or dealer.

(ii) The identification number of the warehouse, farm, or dealer, as applicable, at/from which the tobacco was purchased.

(iii) The address, the producer association number, if applicable, and percentage share of the proceeds of the farm operator and any other producer from whom tobacco was purchased as a nonauction purchase.

(iv) The date of purchase.

(v) The pounds of tobacco purchased.

(vi) The gross purchase price.

(vii) The amount of penalty.

(viii) The amount deducted for the "No Net Cost Tobacco Account."

(ix) The quantity of tobacco purchased from a prior crop and carried over for marketing in a subsequent crop year.

(2) *Sales.* (i) The name and identification number of the:

(A) Warehouse through which the tobacco was sold, if sold at a warehouse auction, or

(B) Buyer if the tobacco was sold at a nonauction sale.

(ii) The date of sale.

(iii) The pounds of tobacco sold.

(iv) The gross sale price.

(c) Nonauction purchase.

(1) Each purchase of tobacco from a producer from a quota producing area shall be identified by a marketing card, issued for the farm on which the tobacco was produced unless an AMS inspection is obtained prior to purchase which shows that tobacco being offered for sale is a kind not subject to marketing quotas.

(2) For burley and flue-cured tobacco:

(i) After each nonauction purchase, the dealer shall enter a declining balance of "103 percent of quota" on the reverse side of the marketing card. The declining balance shall be determined by reducing the previous "103 percent of quota" entry on the marketing card by the number of pounds of tobacco purchased. The date the tobacco was purchased also shall be entered on the marketing card at the time each lot of tobacco is purchased.

(ii) After each nonauction purchase, the dealer shall prepare a form MQ–72–2 which shall set forth the following:

(A) The date of the purchase.

(B) The registration number of the dealer.

(C) The name and address of the person selling the tobacco.

(D) The identification number (farm number, warehouse code, or dealer number, as applicable) of the person selling the tobacco.

(E) The pounds of tobacco purchased.

(F) The amount of penalty collected.

(G) The method (estimating or weighing) of determining the pounds of tobacco marketed.

(H) The signature of the seller and the date signed.

(iii) The dealer shall make deductions for producer marketing assessments to the No Net Cost Tobacco Account as provided for in Part 1464 of this title. For nonauction purchases which are made by the dealer from producers, the dealer shall make a deduction in accordance with Part 1464 of this title from the price paid to the producer for the tobacco. However, a deduction shall not be made if the original "103 percent of quota" entry on the marketing card used to identify the tobacco was zero pounds. The amount of the deduction which is applicable to tobacco marketed during each marketing year will be that amount per pound which is approved and announced by the Secretary as the producer marketing assessments to the No Net Cost Tobacco Account for each such marketing year.

(3) For all other kinds of tobacco:

(i) When a Form MQ–77 Marketing Card is used to identify a nonauction sale, the producer's signature shall be obtained on the reverse side of a sale memo which is a part of the form MQ–77. A nonauction sale not identified by a marketing card shall be identified by a form MQ–82 executed by a marketing recorder or other representative of the State ASC committee. The dealer shall record each nonauction purchase of tobacco on form MQ–79, Dealer's Record.

(ii) The dealer shall make deductions for producer contributions to the No Net Cost Tobacco Account provided for in part 1464 of this title. For nonauction purchases which are made by the dealer from producers, the dealer shall make a deduction in accordance with part 1464 of this title from the price paid to the

producer for the tobacco. However, a deduction shall not be made if the marketing card used to identify a kind of tobacco shows a converted penalty rate of 100 percent. The amount of the deduction which is applicable to such kind of tobacco marketed during each marketing year will be that amount per pound which is approved and announced by the Secretary as the producer contribution to the No Net Cost Tobacco Account or Fund for each such marketing year.

(d) Record and report of purchases and resales. (1) For burley and flue-cured tobacco, each dealer shall keep a record and make reports on Form MQ–79 showing all purchases and resales, excluding tobacco not in the form normally marketed by producers. After each transaction is entered on the Form MQ–79, each dealer shall enter a balance to reflect the pounds of tobacco remaining that may be sold without causing prior resales to exceed prior purchases. Any tobacco sold in excess of such balance shall be considered excess tobacco and subject to a marketing quota penalty at the full penalty rate. The purchaser shall sign the Form MQ–79 on the same line as the transaction is recorded by the dealer who is offering such tobacco for resale. In the event of a purchase or resale of tobacco which is purchased by the dealer from a crop of tobacco produced prior to the current crop, the Form MQ–79 shall be annotated to indicate that such tobacco was so purchased and carried over from a crop produced prior to the current crop.

(2) For all other kinds of tobacco, each dealer shall keep a record and make reports on Form MQ–79 showing all purchases and resales of tobacco made by or for the dealer and, in the event of a purchase or resale of tobacco which is purchased prior to the current crop, the fact that such tobacco was so purchased and carried over from a crop produced prior to the current crop.

(3) A Form MQ–79 shall be prepared and a copy (together with executed copies of Form MQ–72–2 for all nonauction purchases of burley and flue-cured tobacco) shall be forwarded to the State ASCS office not later than the end of the calendar week in which such tobacco was purchased or resold. However, if tobacco is purchased prior to the opening of the local auction market, a Form MQ–79 shall be prepared and a copy, together with executed copies of Form MQ–72–2 for all nonauction purchases, shall be forwarded to the State ASCS office not later than the end of the calendar week which would include the first sale date of the local auction markets. In addition, if tobacco is resold in a State other than where the tobacco is produced and the auction markets at such location open earlier than the auction market where the tobacco normally would be sold at auction by farmers, reports together with executed copies of Form MQ–72–2 for all nonauction purchases shall be prepared and forwarded to the State ASCS office not later than the end of the calendar week which would include the first day of the local auction market where the resale takes place.

(4) The data to be entered on Form MQ–72–2 for nonauction purchases from a producer shall be the data which is enumerated in accordance with the provisions of paragraph (c)(2) of this section.

(5) At the end of the dealer's marketing operation, but not later than April 1 for tobacco other than flue-cured and December 15 for flue-cured tobacco, such dealer shall for each kind of tobacco:

(i) Show the word "final" on the Dealer's Report, MQ–79, for the season,

(ii) Report on such "final" MQ–79 for the season the quantity of tobacco on hand and its location,

(iii) Permit its inspection by a representative of ASCS, and

(iv) Provide for weighing of such tobacco (to be witnessed by a representative of ASCS) and furnish a certification as to the actual weight of such tobacco. After the weight of such tobacco has been determined as provided in this section, it shall be considered as the official weight for comparing purchases and resales for the purpose of determining the amount of penalty, if penalty is due.

(6) Notwithstanding the provisions of paragraph (d)(5) of this section any dealer having tobacco transactions after April 1 for tobacco other than flue-cured and December 15 for flue-cured tobacco, shall make reports on MQ–79 at the end of each week, as provided in paragraph (d)(3) of this section.

(7) For burley and flue-cured tobacco, before the next marketing season begins, carryover tobacco reported by the dealer as provided in paragraph (d)(5) of this section shall be reinspected by a representative of ASCS. When the reinspection indicates an amount of carryover tobacco different from that amount determined by the initial inspection, the dealer shall provide for the weighing of such tobacco which shall be witnessed by an ASCS representative. The dealer shall furnish to such representative at the time of weighing a certification as to the actual weight of such tobacco. If an ASCS representative determines that the weight of the tobacco is different, by reweighing, than the amount reported on the initial weight together with the reweighed quantity after taking into consideration any purchases and resales that occurred subsequent to the initial certification as provided in paragraph (d)(5) of this section shall be used for the purpose of determining penalty, if penalty is due. Penalty shall be assessed, after the initial certification and reconciliation, when the redetermined pounds exceed the amount determined by taking the initial pounds of carryover tobacco plus purchases, minus resales. The redetermined pounds shall be the official pounds to be credited to the account as carryover.

(8) In addition to Form MQ–79 and Form MQ–72–2, if applicable, a Form MQ–79 (Supplemental) shall be executed to record information relating to each purchase of tobacco for which a marketing assessment to the No Net Cost Tobacco Account is deducted from the price paid to the producer for the tobacco. The Form MQ–79 (Supplemental) shall be forwarded to the State ASCS Office at the time of forwarding the Form MQ–79 on which the purchase is recorded. A check, draft, or money order in the amount of the deduction recorded on Form MQ–79 (Supplemental) and drawn payable to Commodity Credit Corporation shall be forwarded to the State ASCS office at the same time as Forms MQ–79 and MQ–79 (Supplemental).

(e) *Daily report to warehouse operator for buyers correction account.* Notwithstanding the provisions of § 723.405 of this part, reports shall be made as follows:

(1) Any dealer, buyer, or any other person receiving tobacco from or through a warehouse operator at an auction sale or otherwise, which is not invoiced to such person or which is incorrectly invoiced to such person by the warehouse operator, shall furnish to the warehouse operator on a daily sales basis an adjustment invoice or buyers settlement sheet.

(2) Each dealer who purchases tobacco on a warehouse floor for any sale day in which there is no adjustment required in the account as shown on the warehouse bill-out invoice for that sale day, shall file a negative report with the warehouse operator for that sale day.

(3) Such reports as required under paragraphs (d) (1) and (2) of this section shall be furnished daily, if practicable (otherwise, they shall be furnished at the end of each week), and shall show the identification number of the

warehouse where the purchase was made.

(f) *Reporting of processed tobacco.* Any dealer who delivers tobacco to a firm for the purpose of redrying, processing or stemming of such tobacco shall, by the end of the week in which such tobacco was delivered, report to the State ASCS office on MQ–79, Dealer's Report:

(1) The date delivered;

(2) Name and address of the firm to which the tobacco was delivered, and

(3) Pounds of tobacco (green weight) delivered which shall be entered in the resales pounds column. Such tobacco shall be considered as a resale on the date of delivery for the purpose of balancing the dealer account and collection of penalties where penalties are due.

(g) *Tobacco represented to be a nonquota kind.* Any dealer who plans to purchase tobacco that was produced on a farm in a quota area shall treat such tobacco as a quota kind of tobacco according to the provisions of this part 723 unless prior to the purchase a certification is obtained from an AMS inspector to indicate that such tobacco is a nonquota kind of tobacco. In such case, the dealer shall mail or otherwise deliver to the State ASCS office, on the date of the purchase, a copy of the AMS certification and a statement signed by the AMS inspector, the producer, and the dealer to indicate the:

(1) State and county code and farm number of the farm on which the tobacco was produced.

(2) Name and address of the producer.

(3) Name and address of the dealer.

(4) Weight of the tobacco.

§ 723.405 Dealers exempt from regular records and reports on MQ–79; and season report for dealers.

(a) Any dealer or buyer who acquires tobacco in the form in which tobacco ordinarily is sold by farmers and resells 5 percent or less of any such tobacco shall not be subject to the requirements of § 723.404 of this part except for the requirements which relate to the reporting of nonauction purchases from producers and the requirements of § 723.404(e) of this part. A dealer or buyer whose resales in the form normally marketed by producers farmers exceed 5 percent of their purchases as a direct result of order buying for another dealer for a service fee may report under paragraph (b) of this section in lieu of § 723.404 of this part (except for requirements which relate to nonauction purchases from producers and requirements of § 723.404(e) of this part.

(b) (1) This paragraph is applicable only to burley and flue-cured tobacco. Each dealer or buyer shall make a report to the Director, not later than February 1 of each year for flue-cured and April 1 for burley tobacco, showing by States where acquired, source and pounds of all tobacco, in the form normally marketed by producers, purchased at auction or nonauction including tobacco received which was not billed to the dealer or buyer. Any acquisition of tobacco in the form normally marketed by producers by the dealer or buyer during the marketing year (October 1 through September 30 for burley tobacco and July 1 through June 30 for flue-cured tobacco) which is not included in the initial report shall be reported in like manner no later than the end of the calendar week following the week in which the tobacco was acquired. The report shall show:

(2) For purchases at auction for each warehouse;

(i) USDA registration number (warehouse code),

(ii) Name and address of warehouse,

(iii) Gross pounds originally billed to the buyer,

(iv) Gross pounds billed to the buyer for which payment was made,

(v) Gross pounds from the company correction account deducted for short lots and short weights and returned lots, and

(vi) Gross pounds from the company correction account added for long lots and long weights.

(3) For purchases at nonauction;

(i) Name and address of seller (dealer or farmer),

(ii) Seller's number (dealer's registration number or farm number, including State and county code), and

(iii) Pounds purchased.

§ 723.406 Provisions applicable to damaged tobacco or to purchases of tobacco from processors or manufacturers.

(a) *Damaged tobacco.* Any dealer, warehouse operator, or other person who plans to purchase tobacco that was damaged by fire, water, or any other cause shall prior to purchase report such plans to the State ASCS office issuing Form MQ–79, Dealer's Record Book. Such report shall be timely made so that an ASCS representative can determine the marketable value of such damaged tobacco, and so that the weighing and removal of such tobacco can be witnessed by an ASCS representative. Any damaged tobacco purchased before such plans are reported to the State ASCS office and before such tobacco is inspected by an ASCS representative shall be deemed excess tobacco and penalty at the full rate shall be due.

(b) *Purchase from processor or manufacturer.* Any tobacco purchased by a dealer, warehouse operator, or other person from a processor or manufacturer shall be considered to be tobacco in the form not normally marketed by producers unless the purchaser obtains from the processor or manufacturer a certification stating that such purchased tobacco is in the form normally marketed by producers. The certification by the processor or manufacturer shall be on a form prescribed by the Deputy Administrator certifying to ASCS that the tobacco involved in the transfer of ownership is in the form normally marketed by producers. No purchase credit shall be given to a dealer, warehouse operator, or other person on MQ–79, Dealer's Record Book, for any purchase of tobacco which is not in the form normally marketed by producers. Tobacco which meets the definition of pickings as defined in this part shall be considered tobacco in the form not normally marketed by producers.

(c) *Report by dealer or warehouse operator.* Any dealer, warehouse operator or other person who plans to purchase tobacco in the form normally marketed by producers from a processor or manufacturer shall, prior to purchase, report such plans to the State ASCS office issuing form MQ–79, Dealer's Record Book, to such person. Such report shall be made timely so that a representative of ASCS may inspect the tobacco to determine its marketable value and whether the tobacco is in the form normally marketed by producers. Any tobacco purchased from processors or manufacturers before such plans are reported to the state ASCS office and before the tobacco is inspected by an ASCS representative or an inspection is declined by an ASCS representative shall be deemed excess tobacco and the penalty at the full rate shall be due.

(d) *Report by processor or manufacturer.* Each processor or manufacturer shall make a report to the Director, showing the quantity of tobacco sold in the form not normally marketed by producers to dealers and buyers other than processors or manufacturers. The report shall be filed no later than the end of the calendar week following the week in which such tobacco was sold and shall show the name of the purchaser, the date of the sale and the pounds sold.

§ 723.407 Cigar tobacco buyer's records and reports.

(a) *This section is applicable to buyers of cigar tobacco.*—(1) *Definition of cigar buyer.* With respect to this

section, a buyer is any person who buys cigar tobacco including an association or cooperative that receives tobacco from producers for the purpose of:

(i) Selling it for the producers, or

(ii) Placing it under price-support loan through Commodity Credit Corporation.

(2) *Report of buyer's name and address.* Each buyer shall properly execute, detach, and promptly forward to the State ASCS office, "Receipt for Buyer's Record" contained in MQ–79 (CF&B), which is issued to the buyer.

(b) *Record of purchases.* A buyer shall keep records which provide the following information for each lot of each kind of tobacco purchased or sold by the buyer, including tobacco obtained from grading tobacco for producers or furnishing curing space, or stripping space:

(1) The name of:

(i) The operator of the farm on which the tobacco was produced; or

(ii) The name and address of the seller, in the case of a sale by a person other than the farm operator.

(2) The identification number of the farm at/from which the tobacco was purchased.

(3) The date of purchase.

(4) The pounds of tobacco purchased.

(5) The gross purchase price.

(6) The amount of penalty.

(7) The amount deducted for "No Net Cost Tobacco Account or Fund."

(c) *Report of sales.* Each buyer shall maintain records which will show, by kind of tobacco, the disposition of tobacco purchased under paragraph (b) of this section.

(d) *Deductions for producer contributions.* The buyer shall make deductions for producer contributions to the No Net Cost Tobacco Account or Fund as provided in part 1464 of this title. For nonauction purchases which are made by the dealer from producers, the buyer shall make a deduction in accordance with part 1464 of this title from the price paid to the producer for the tobacco. However, a deduction shall not be made if the marketing card used to identify the tobacco shows a converted penalty rate of 100 percent. The amount of the deduction which is applicable to such kind of tobacco marketed during each marketing year will be that amount per pound which is approved and announced by the Secretary as the producer contribution to the No Net Cost Tobacco Account or Fund for each such marketing year.

(e) *Identification of sale or marketing card memo and buyers records.* Each MQ–76 and each sale memo from an MQ–77 used to identify each sale of tobacco by a producer shall be properly executed by the buyer. The serial number of the MQ–76 marketing card or sale memo from an MQ–77 to identify such tobacco, shall be recorded on the buyer's copy of the MQ–79 (CF&B) and on the check register or check stub for the check written with respect to such tobacco.

(f) *Record and report of purchases of tobacco from producers.* (1) Each buyer shall keep a record and make reports on MQ–79 (CF&B), Buyer's Record, showing by kinds of tobacco purchased by or for such buyer from producers. Such record and report shall show for each sale the sale date, the name of the farm operator, (and the name and address of the person selling the tobacco if other than the operator), the serial number of the within quota marketing card (MQ–76), and from each excess card (MQ–77), the sale memo number used to identify the sale, the pounds of tobacco represented in the sale, the rate of penalty shown on the sale memo (MQ–77), and the amount of penalty. If a marketing card is not presented by the producer, the buyer shall record and report the purchase as provided above except that the buyer shall enter the word "None" in the space for the serial number of the marketing card (MQ–76) or sale memo (MQ–77), the applicable rate of penalty per pound in the space for rate of penalty, and shall show the name and address of the seller in the space for the seller's name.

(2) The original of MQ–79 (CF&B), excess sale memos (MQ–77), and a remittance for all penalties shown by entries on MQ–79 (CF&B) and on the excess sale memos (MQ–77) to be due shall be forwarded to the State ASCS office not later than the 10th day of the calendar month next following the month during which the sale date occurred.

(3) In addition to Form MQ–79 a Form MQ–79 (Supplemental) shall be executed to record information relating to each purchase of tobacco for which a contribution to the No Net Cost Tobacco Account or Fund is deducted from the price paid to the producer for the tobacco. The Form MQ–79 (Supplemental) shall be forwarded to the State ASCS office at the time of forwarding the Form MQ–79 on which the purchase is recorded. A check, draft, or money order in the amount of the deduction recorded on Form MQ–79 (Supplemental) and drawn payable to Commodity Credit Corporation shall be forwarded to the State ASCS office at the same time as Form MQ–79 and MQ–79 (Supplemental).

§ 723.408 Producer's records and reports.

(a) *Failure to file reports or filing false reports.* (1) With respect to any kind of tobacco, if the producer on a farm files an incomplete or incorrect report, fails to file a report, or files or aids or acquiesces in the filing of any false report with respect to the amount of such kind of tobacco produced on or marketed from the farm, applicable tobacco acreage allotment or burley farm marketing quota next established for such farm shall be reduced, unless the county and State ASC committees determine, according to instructions issued by the Deputy Administrator, that such reduction is not required.

(2) For all kinds of tobacco except burley tobacco, if a farm operator files a report of acreage of the applicable kind of tobacco on the farm and, after a determination of the acreage, it is determined by the county ASC committee (with approval of the State ASC committee) that the report was false (either significantly under reported or significantly over reported by more than the tolerance for reporting as provided in part 718 of this chapter) in what amounts to a scheme or device to defeat the purpose of the program, the allotment next established for the farm shall be reduced by an amount determined by multiplying the acreage falsely reported (difference between reported and determined acreage) by:

(i) With respect to flue-cured tobacco, the farm yield established for the farm for the year in which the false report was filed, or

(ii) For any other kind of tobacco, the actual yield per acre for the year in which the false report was filed.

(b) *Harvesting second crop tobacco from the same farm.* For all kinds of tobacco except burley, if in the same calendar year more than one crop of tobacco was grown from:

(1) The same tobacco plants, or

(2) Different tobacco plants, and is harvested for marketing from the same acreage of a farm, the acreage allotment next established for such farm shall be reduced by an amount equivalent to the acreage from which more than one crop of tobacco was so grown and harvested.

(c) *False identification.* If there is false identification of any kind of tobacco, the applicable farm acreage allotment or farm marketing quota next established for the farm and kind of tobacco involved shall be reduced, except that such reduction for any such farm shall not be made if the county and State ASC committees determine, according to instructions issued by the Deputy Administrator, that such reduction is not required.

(d) *Report on marketing card.* (1) The operator of each farm on which tobacco is produced shall return to the county ASCS office each marketing card issued

for the farm whenever marketings from the farm are completed and, in no event, later than,

(i) June 1 of the marketing year in the case of cigar tobacco, and

(ii) For all other kinds of tobacco, not later than 20 days after the close of the tobacco auction markets for the marketing year for the locality in which the farm is located. Failure to return the marketing card within 15 days after written request by certified mail from the county ASCS executive director shall constitute failure to account for disposition of all tobacco marketed from the farm unless disposition of tobacco marketed from the farm is otherwise accounted for to the satisfaction of the county ASC committee.

(2) For all kinds of tobacco except burley and flue-cured:

(i) At the time the marketing card is returned to the county ASCS office, the farm operator must certify with respect to each:

(A) MQ–77, to the quantity of tobacco on hand and its location.

(B) MQ–76, to the accuracy of the Record of Sales recorded on the card.

(ii) Failure of the farm operator to make the applicable certification shall constitute failure to satisfactorily account for the disposition of tobacco marketed from the farm.

(3) Upon failure to satisfactorily account to the county ASC committee for disposition of tobacco marketed from the farm the allotment or quota next established for such farm and such kind of tobacco shall be reduced, except that such reduction for any such farm shall not be made if it is established to the satisfaction of the county ASC committee and a representative of the State ASC committee that the failure to furnish such proof of disposition was unintentional and no producer on such farm could reasonably have been expected to furnish such proof of disposition. However, such failure will be construed as intentional unless such proof of disposition is furnished and payment of all additional penalty is made, or no person connected with such farm for the year for which the acreage allotment or quota is being established caused, aided, or acquiesced in the failure to furnish such proof.

(e) *Report of production and disposition.* (1) In addition to any other reports which may be required by this subpart, the operator or any producer on a farm (even though the harvested acreage does not exceed the acreage allotment or even though no farm acreage allotment or farm marketing quota was established for the farm) shall, upon written request by certified mail from the State or county ASC committee, furnish on MQ–108, Report of Production and Disposition, a written report of the acreage, production and disposition of all tobacco produced on the farm by sending the same to the State or county ASC committee within 15 days after the request was mailed showing as to the farm at the time of filing such report with respect to the applicable kind of tobacco the:

(i) Total harvested acres,

(ii) Total amount of tobacco on hand and its location,

(iii) Total pounds of tobacco produced,

(iv) Name and address of the warehouse operator, dealer, or other person to or through whom tobacco was marketed, and the number of pounds marketed, the gross price paid and the date of the marketings, and

(v) Complete details as to any tobacco disposed of other than by sale.

(2) With respect to any farm on which burley or flue-cured tobacco was produced or available for marketing from carryover tobacco, the operator or any producer on the farm (even though the harvested acreage does not exceed the flue cured farm acreage allotment or even though no farm acreage allotment or farm marketing quota was established for the farm) shall, upon written request from the county ASC committee, furnish on Form MQ–108–1, Report of Unmarketed Tobacco, a written report of the amount and location of the applicable kind of tobacco produced on the farm which is unmarketed at the end of the marketing season and the amount the applicable kind of tobacco produced by such operator or producer on any other farm, which is unmarketed at the end of the marketing season and which is stored on the farm, by sending the report to the county ASC committee within 15 days after the request was mailed to such person at such person's last known address.

(3) Failure to file the MQ–108 or MQ–108–1 as requested, or the filing of MQ–108 or MQ–108–1 which is found by the State or county ASC committee to be incomplete or incorrect shall, to the extent that it involves tobacco produced on the farm, constitute failure to account for the disposition of tobacco produced on the farm and the allotment or quota next established for such farm shall be reduced, except that such reduction shall not be made if it is established to the satisfaction of the county or State ASC committee that failure to furnish such proof of disposition was unintentional and no producer on such farm could reasonably have been expected to furnish such proof of disposition: However, such failure will be construed as intentional unless such proof of disposition is furnished and payment of all additional penalty is made, or no person connected with such farm for the year for which the farm acreage allotment or farm marketing quota is being established caused, aided, acquiesced in the failure to furnish such proof.

(f) *Reports by producer-manufacturers.* (1) For all kinds of tobacco except burley and flue-cured tobacco, each producer who manufactures tobacco products from tobacco produced by or for such person as a producer, shall report to the State ASCS office with respect to each farm on which such tobacco is produced and as soon as all tobacco from the farm has been weighed as follows:

(i) If the harvested acreage is within the allotment, the producer-manufacturer shall report the total pounds of tobacco produced, the date(s) on which such tobacco was weighed, the farm serial number of the farm on which it was produced, and the estimated value of such tobacco.

(ii) If the harvested acreage is in excess of the allotment, the producer-manufacturer shall report the total pounds of tobacco produced on the farm, the date(s) on which the tobacco was weighed, the farm serial number of the farm on which it was produced, the estimated value of the tobacco, and the location of the tobacco. If the required reports are not made, penalty shall be paid on the tobacco by the producer-manufacturer, at the converted rate of penalty shown on the marketing card issued for the farm, when it is moved from the place where it can be conveniently inspected by the county ASC committee at any time separate and apart from any other tobacco.

(2) If the producer-manufacturer has excess tobacco and does not pay the penalty thereon at the converted rate of penalty shown on the marketing card, such producer-manufacturer shall notify in writing the buyer of the manufactured product or the buyer of any residue resulting from processing the tobacco, at time of sale of such product or residue, of the precise amount of penalty due on such manufactured product or residue. In such event, the producer-manufacturer shall immediately notify the State ASCS executive director and shall account for the disposition of such tobacco by furnishing the State ASCS executive director a report on a form to be furnished by such State ASCS executive director, showing the name and address of the buyer of the manufactured products or residue, a detailed account of the disposition of

such tobacco and the exact amounts of penalty due with respect to each such sale of such products or residue to indicate, together with copies of the written notice that was given to the buyer of such products or residue to indicate the exact amount of the penalty due.

(3) Failure to file the report required in paragraph (f)(2) of this section, or the filing of a report which is found by the State ASC committee to be incomplete or incorrect, shall be considered failure of the producer-manufacturer to account for the disposition of tobacco produced on the farm and the allotment next established for the farm shall be reduced for such failure, except that such reduction for any such farm shall not be made if it is established to the satisfaction of the county and State ASC committees, that:

(i) The failure to furnish such report of disposition was unintentional and the producer-manufacturer on such farm could not reasonably have been expected to furnish such report of disposition. However such failure will be construed as intentional unless such report of disposition is furnished and payment of all additional penalty is made, or

(ii) No person connected with such farm for the year for which the allotment is being established caused, aided, or acquiesced in the failure to furnish such report. The producer-manufacturer shall be liable for the payment of penalty.

(g) *Amount of allotment or quota reductions*—(1) *Burley tobacco.* For burley tobacco, the farm marketing quota determined for a farm for the current year shall be reduced by that amount of tobacco which is involved in a marketing quota violation as described in paragraphs (a), (b), (c), (d), or (e), of this section which occurred in any prior year. However, the amount of such reduction shall not exceed the current year farm marketing quota. The county ASC committee shall determine the amount of tobacco involved in the marketing quota violation. If the actual quantity of tobacco involved in such violation is unknown, the county ASC committee shall determine the quantity by considering both the condition of the crop during production, if known, and such other information as is available.

(2) *Kinds of tobacco except burley tobacco.* The amount of reduction in the allotment for the current year for a violation described in paragraphs (a), (c), (d), (e), or (f) of this section shall be that percentage, but not to exceed 100 percent, which the amount of the tobacco involved in the violation is of the respective farm marketing quota for the farm for the year in which the violation occurred times the current year farm acreage allotment. The quantity of tobacco in violation shall be determined by the county ASC committee. If known, the actual quantity shall be determined by the county ASC committee to be the amount of tobacco involved in the violation. If the actual quantity is unknown, determine the quantity by taking into consideration the condition of the crop during production, if known, and such other information that is available.

(h) *Allotment or quota reduction for combined farms.* If the farm involved in the violation is combined with another farm prior to the reduction, the allotment or quota reduction shall be applied as heretofore provided in this section to that portion of the farm acreage allotment or farm marketing quota for which a reduction is required.

(i) *Allotment or quota reduction for divided farms.* If the farm involved in the violation has been divided prior to the reduction, the reduction shall be applied as heretofore provided in this section to the allotments or quota for the divided farms required to be reduced.

(j) *Quota reductions for flue-cured tobacco.* For flue-cured tobacco only, if an acreage allotment reduction is made under this section, the marketing quota shall be reduced to reflect such reduction in an amount determined by multiplying the acreage reduction by the farm yield.

(k) *County administrative hearing in connection with violations.* Except for the failure to return a marketing card, the allotment or quota for any farm shall not be reduced for a violation under this section until the operator of the farm has been afforded an opportunity to discuss the nature and extent of the violation with the county ASC committee. If after having been afforded an opportunity to discuss a violation with the county ASC committee the farm operator fails or refused to discuss the violation, the county ASC committee shall take action as required by this part.

(l) *Sequence of allotment or quota reductions.* For burley and flue-cured tobacco, if the tobacco farm acreage allotment or farm marketing quota for a farm is to be reduced in the current year because of both:

(1) A violation, and

(2) Overmarketings in a prior year, the reduction in the farm acreage allotment or farm marketing quota for the violation shall be made before making the reduction for overmarketings.

(m) *Correction of farm records.* For burley and flue-cured tobacco, where farm data for actual marketings are determined to be incorrect because of a violation, the records shall be corrected for each farm on which the tobacco was produced, and for each farm whose card was used to identify marketings.

(n) *Report on Form MQ–92, Estimate of Production.* An estimate of production, Form MQ–92, shall be prepared immediately prior to harvest for each farm for which the county or State ASC committee or a representative of the county or State ASC committee believes than an MQ–92 for the farm would be in the best interests of the program. The county ASC committee shall have the authority to visit any farm for the purposes of making an estimate of production or determination of planted acreage needed to complete an estimate of production.

(o) *Effect of false identification on establishing future farm marketing quotas.* Notwithstanding any other provision of this section, with respect to burley or flue-cured tobacco, if a producer falsely identifies such tobacco as having been produced on or marketed from a farm, the quantity of the tobacco which is falsely identified shall be considered, for the purpose of establishing future farm marketing quotas, as having been produced on both the farm for which it was identified as having been produced, and the farm of actual production, if known, or, as the case may be, such quantity of tobacco shall be considered as actually marketed from the farm.

§ 723.409 Producer penalties; false identification and related issues.

(a) *Penalties for marketing over 103 percent of farm quota-burley and flue-cured tobacco.* For burley and flue-cured tobacco, a penalty at the full rate shall be due on any marketings which exceeds 103 percent of the effective farm marketing quota.

(b) *Penalties for false identification or failure to account-burley tobacco*—(1) *For burley tobacco.* If any producer falsely identifies or fails to account for the disposition of any tobacco produced on a farm, penalty at the full rate shall be due on the larger of the:

(i) Actual marketings above 103 percent of the effective farm marketing quota, or

(ii) Amount of tobacco equal to 25 percent of the effective farm marketing quota. The requirement of paragraph (b)(ii) of this section shall not be applied if the county ASC committee determines with concurrence of State ASC committee, that assessment of penalty based on 25 percent of the effective farm marketing quota would be unduly harsh when compared with the pounds in

violation and no adverse effect on the program would result.

(2) *For flue-cured tobacco.* If any producer falsely identifies or fails to account for the disposition of any tobacco produced on the farm, a penalty at the full rate shall be assessed on the larger of:

(i) The actual marketings above 103 percent of the effective farm marketing quota; or

(ii) The sum of pounds equal to 25 percent of the effective farm marketing quota plus the pounds determined by multiplying the farm yield times the acres harvested in excess of the effective farm acreage allotment. If such amount exceeds the amount determined in accordance with paragraph (b)(2)(i) of this section the penalty assessed may be based on the amount determined in accordance with such paragraph if the county ASC committee determines, with the concurrence with the State ASC committee, that the penalty assessed on the amount determined in accordance with this paragraph would be unduly harsh in relation to the quantity of tobacco which is falsely identified or which is not accounted for and the tobacco program would not be adversely effected.

(3) *For kinds of tobacco other than burley or flue-cured tobacco.* (i) If any producer falsely identifies or fails to account for the disposition of any kind of tobacco produced on a farm, an amount of tobacco equal to the normal yield of the number of acres harvested in the current year in excess of the farm acreage allotment for the kind of tobacco shall be deemed to have been marketed from such farm.

(ii) If any producer who manufactures tobacco products from tobacco produced by or for such person fails to make the reports or makes a false report, the producer shall be deemed to have failed to account for the disposition of tobacco produced on the farm(s) involved. The filing of a report by a producer under § 723.408 of this part which the State ASC committee finds to be incomplete or incorrect, shall constitute a failure to account for the disposition of tobacco produced on the farm.

(c) *Canceled allotment or quota.* If part or all of the tobacco produced on a farm has been marketed and the farm acreage allotment or farm marketing quota for the farm is canceled, any penalty due on the marketings shall be paid by the producers.

(d) Overmarketing proportionate share of effective farm marketing quota-burley or flue-cured tobacco. With respect to burley or flue cured tobacco, if the county ASC committee determines that the farm operator or another producer on the farm has marketed more than 103 percent of such operator's or producer's share of the effective farm marketing quota with intent to deprive some other producer on the farm from marketing such producer's proportionate share of the same crop of tobacco, such operator or other producer shall be liable for marketing penalties at the full rate per pound for each pound of tobacco marketed above 103 percent of such producer's share of the effective farm marketing quota. However, the sum of such penalties shall not exceed the total penalties due on total marketings above 103 percent of the effective farm marketing quota for the farm on which such tobacco was produced. Before assessment of penalty pursuant to this paragraph, a hearing shall be scheduled by the county ASC committee and the operator and affected producers shall be invited to be present, or to be represented, to determine whether the operator or another producer on the farm has marketed more than 103 percent of such person's proportionate share of the effective farm marketing quota. The notice of the hearing shall request the farm operator and affected producers to bring to the hearing floor sheets and other relevant supporting documents. At least two members of the county ASC committee shall be present at the hearing. The hearing shall be held at the time and place named in the notice and any action taken to impose penalty shall be taken after the hearing. If the farm operator or other affected producer does not attend the hearing, or is not represented, the county ASC committee shall make a determination on the basis of available records and shall assess any penalties that may be required against the applicable person.

(e) *Penalties not to be assessed-burley or flue-cured tobacco.* With respect to burley or flue-cured tobacco, if the operator or another producer on the farm markets a quantity of tobacco above 103 percent of the effective farm marketing quota for the farm and such overage is found to have been caused by the failure to record or improper recording of tobacco poundage data on the marketing card, that amount of the penalty as was due to such failure to record or improper recording will not be required to be paid by the farm operator or other producer if:

(1) For amounts of $10 or less, the county ASC committee, and

(2) For amounts over $10, the county ASC committee, with the approval of the State ASC committee, determines that each of the following conditions is applicable:

(i) The failure to record or incorrect recording resulted from action or inaction of a marketing recorder or another ASCS employee, and

(ii) The farm operator or another producer on the farm had no knowledge of such failure or error. Overmarketings for a farm for which the marketing penalty will not be paid pursuant to the provisions of this paragraph shall be determined based upon the correct effective farm marketing quota and correct actual marketings of tobacco from the farm.

(f) *Ineligible for price support.* A penalty at the full rate announced for a kind of tobacco for the current marketing shall be assessed on any marketing of any kind of tobacco by any producer on a farm if such producer is ineligible for price support because the farm operator or other producer on the farm has not agree to make a contribution to the No Net Cost Fund or pay an assessment to the No Net Cost Account, as applicable, in accordance with part 1464 of this title.

(g) *Person to pay penalty when erroneous rate is shown on card (except burley and flue-cured tobacco).* If an erroneous penalty rate is shown on a marketing card and tobacco is identified by such card, the producer shall remit any additional penalty due for the sale.

§ 723.410 Penalties considered to be due from a warehouse operator, dealers, buyers, and others excluding the producer.

Any marketing of tobacco under one of the following conditions shall be considered to be a marketing of excess tobacco.

(a) *Auction sale without burley or flue-cured tobacco marketing card.* For burley and flue-cured tobacco, any first marketing of tobacco at an auction sale by a producer which is not identified by a valid marketing card at the time of marketing shall be considered to be a marketing of excess tobacco and the penalty thereon shall be collected and remitted by the warehouse operator unless prior to marketing, an AMS inspection certificate is obtained showing that the tobacco is of a kind not subject to marketing quotas.

(b) *Auction sale without dark air-cured, fire-cured, or Virginia sun-cured tobacco marketing card.* For dark air-cured, fire-cured, or Virginia sun-cured tobacco, any first marketing of tobacco at an auction sale by a producer which is not identified by a valid marketing card [MQ–76 or MQ–77 (including sale memo)] on or before the last warehouse sale day of the marketing season, or within 4 weeks following the date of marketing, whichever comes first, shall

be identified by an MQ–82, and shall be presumed, subject to rebuttal, to be a marketing of excess tobacco. The penalty thereon shall be paid by the warehouse operator.

c. *Burley or flue-cured tobacco nonauction sale.* For burley and flue-cured tobacco, any nonauction marketing of tobacco which:

(1) Is not identified by a valid marketing card and recorded at the time of marketing on MQ–79, Dealer's Report, the marketing card, and MQ–72–2, Report of Tobacco Nonauction Purchase; or,

(2) If purchased prior to the opening of the local auction market for the current year, it is not identified by a valid marketing card and recorded on MQ–79, the marketing card, and MQ–72–2, Report of Tobacco Nonauction Purchase not later than the end of the calendar week which includes the first sale day of the local auction markets, shall be considered a marketing of excess tobacco. The penalty thereon shall be collected by the purchaser of such tobacco, and remitted with MQ–79, unless prior to marketing an AMS inspection certificate is obtained showing that the tobacco is of a kind not subject to marketing quotas.

(d) *Nonauction sale, except burley, flue-cured, and cigar tobacco.* For dark air-cured, fire-cured, or Virginia sun-cured tobacco, any nonauction sale of tobacco which:

(1) Is not identified by an MQ–76 or MQ–77 (including a valid sale memo); and

(2) Recorded on MQ–79, Dealer's Record, not later than the end of the calendar week in which the tobacco was purchased; or

(3) If purchased prior to the opening of the local auction market for the current year, is not identified by an MQ–76 or MQ–77 (including a valid sale memo) and recorded on MQ–79 not later than the end of the calendar week which includes the first day of the local auction markets, shall be presumed, subject to rebuttal, to be a marketing of excess tobacco. The penalty thereon shall be paid by the purchaser of such tobacco.

(e) *Failure to obtain an MQ–76 and sale memo, and failure to record a sale on MQ–76-cigar tobacco.* Any sale of cigar tobacco for which a dealer:

(1) If within quota, fails to record the sale on the marketing card issued for the farm, or

(2) If the tobacco was produced on a farm for which an excess marketing card was issued, fails to obtain a valid sale memo by the end of the sale date, shall be presumed, subject to rebuttal, to be a marketing of excess tobacco. The penalty thereon shall be paid by the buyer who fails to make the required record.

(f) *Leaf account tobacco.* If warehouse resales exceed prior leaf account purchases, such marketings shall be considered to be a marketing of excess tobacco unless such warehouse operator furnishes evidence acceptable to the State ASC committee showing that such marketing is not a marketing of excess tobacco. However, evidence acceptable to the State ASC committee shall not be based on the warehouse operator's proof of purchase of tobacco that is not in the form normally marketed by producers even though such evidence indicates that resales exceed prior leaf account purchases as a result of the blending of tobacco, which was not in the form normally marketed by producers, with the warehouse operator's prior purchases of leaf account tobacco.

(g) *Dealer tobacco-burley or flue-cured.* The burley or flue-cured tobacco resales by a dealer (as shown or due to be shown on Form MQ–79), which are in excess of such dealer's total prior purchases of the respective kind of tobacco (as shown or due to be shown on Form MQ–79) shall be considered to be a marketing of excess tobacco and penalty thereon shall be due at the time the marketing takes place which results in the excess. If the resale which results in penalty being due is made at auction, the warehouse shall deduct the penalty from the proceeds of the sale and shall remit the penalty to the marketing recorder. Penalty due which is not withheld by a warehouse operator shall be remitted weekly by the dealer to the State ASCS office with his reports on Form MQ–79.

(h) *Resales not reported.* Any resale of tobacco which is required to be reported by a warehouse operator or dealer, but which is not reported within the time and in the manner required, shall be considered to be a marketing of excess tobacco, unless and until such warehouse operator or dealer furnishes proof of such resale which is acceptable to the State ASCS executive director. The penalty thereon shall be paid by the warehouse operator or dealer who fails to make the report as required.

(i) *Marketing falsely identified by a person other than the producer of the tobacco.* If any marketing of tobacco by a person other than the producer is identified by a marketing card other than the marketing card issued for the farm on which the tobacco was produced, and the source of production of the tobacco is unknown, such marketing shall be presumed, subject to rebuttal, to be a marketing of excess tobacco. The marketing quota penalty shall be paid by the person who marketed the tobacco.

(j) *Carryover tobacco, except cigar tobacco.* Any tobacco on hand, except for cigar tobacco, and reported or due to be reported under § 723.403 of this part for warehouse operators and § 723.404 of this part for dealers shall be included as a resale in determining whether an account for a kind of tobacco has excess resales. Unless the warehouse operator furnishes proof acceptable to the State ASC committee and unless the dealer furnishes proof acceptable to the State ASCS executive director, showing that such account does not represent excess tobacco, penalty at the full rate for the respective kind of tobacco shall be paid thereon by such warehouse operator or dealer.

(k) *Unrecorded sale of cigar tobacco.* Any sale of cigar tobacco which is not recorded on MQ–79 (CF&B), Buyer's Record Book, by the 10th day of the month following the month during which the sale dated occurred shall be presumed, subject to rebuttal, to be a marketing of excess tobacco. The penalty thereon shall be paid by the buyer who fails to make the record.

(l) *Floor sweepings.* Any person who markets floor sweepings in excess of allowable floor sweepings shall be subject to a civil penalty of 150 percent of the average market price for the immediately preceding marketing year, as determined by the U.S. Department of Agriculture. The calculated penalty rate shall be rounded to the nearest whole cent. Any floor sweepings on hand more than 30 days (15 days with respect to flue cured tobacco) after the warehouse closes for the auction season shall be considered marketed. The floor sweepings on hand shall be weighed by the warehouse operator and the weight shall be certified by the warehouse operator, such weighing to be done in the presence of a representative of either the county ASC committee or State ASC committee. Floor sweepings which are destroyed in the presence of a representative of the county ASC committee, within 30 days (15 days with respect to flue-cured tobacco) after the warehouse closes shall not be considered as marketed when determining the quantity of floor sweepings marketed. If the county ASC committee determines, after the warehouse has been closed for the auction season for more than 30 days (15 days with respect to flue-cured tobacco), that the cumulative quantity of floor sweepings marketed and considered marketed in the current marketing year is in excess of the allowable floor sweepings, the person responsible for

such marketings shall be given notice of the determination and shall be afforded an opportunity to request reconsideration of such determination in accordance with the provisions of part 780 of this chapter. A determination that a civil penalty is due for marketing floor sweepings in excess of the allowable floor sweepings shall not become final and shall not be assessed until such person has been afforded an opportunity for a hearing and such person has exhausted the applicable administrative remedies. The notice of assessment shall require such person to pay the civil penalty to the "Agricultural Stabilization and Conservation Service, USDA" within 15 days after the mailing of the notice.

(m) *Blending tobacco not in the form normally marketed by producers-burley and flue-cured tobacco.* Tobacco purchased from processors or manufacturers that is considered not in the form normally marketed by producers that is blended with tobacco in the form normally marketed by producers shall not be credited as a purchase to the dealer's or warehouse operator's account by the State ASC committee when reconciling the warehouse operator's leaf account or the dealer's purchases and resales. Tobacco not in the form normally marketed by producers that is blended with other tobacco shall be deemed to be excess tobacco and penalty shall be due on the pounds of tobacco by which a warehouse operator's or dealer's resales exceed prior purchases.

§ 723.411 Records and reports regarding hauling, processing, and storage of tobacco.

(a) *Trucker records.* Each trucker shall keep such records as will enable such trucker to furnish the State ASCS office a report with respect to each lot of tobacco received by such trucker showing:

(1) The name and address of the producer;

(2) The date of receipt of the tobacco;

(3) The number of pounds received;

(4) The location where received; and

(5) The name and address of the person to whom it was delivered.

(b) *Processor records.* Each firm engaged in the business of processing tobacco shall keep records with respect to each lot of tobacco received by such firm showing:

(1) The name and address of producer, dealer, warehouse operator, or other person for whom the tobacco was received.

(2) The date of receipt of tobacco.

(3) The number of pounds (green weight) received.

(4) The purpose for which tobacco was received (redrying or stemming)

(5) The amount of any advance or loan made by such person on the tobacco.

(6) The disposition of the tobacco including the net weight of the tobacco processed and the number of containers by classification (strips, stems, scrap or leaf.)

(7) Person to whom delivered and pounds involved.

Any such firm shall report this information to the State ASCS office of the State in which the business is located within 15 days of the end of the marketing year, except for tobacco handled for an association operating the price support program and tobacco purchased at auction or tobacco which was previously reported on Form MQ–79. Where such firm qualifies for the exemption in § 723.405 of this part, such firm is required to report only such tobacco received that does not belong to such firm.

(c) *Records for stored tobacco.* Each firm engaged in storing unprocessed tobacco shall keep records with respect to each lot of unprocessed tobacco received by such firm showing:

(1) The name and address of producer, dealer, warehouse operator, marketing agent or other person for whom the tobacco was received

(2) The date and receipt of the tobacco;

(3) The number of pounds received;

(4) The amount of any advance or loan made by such firm;

(5) The disposition of the tobacco; and

(6) The person to whom delivered and the pounds involved.

Any such firm shall report this information to the State ASCS office of the State in which the business is located within 15 days of the end of the marketing year, except for tobacco handled for an association operating the price support program and tobacco purchased by such firm at auction or for which such firm had previously reported on Form MQ–79. Where such firm qualifies for the exemption in § 723.405 of this part, the firm is only required to report such tobacco received for storage that does not belong to such firm.

§ 723.412 Separate records and reports from persons engaged in tobacco related businesses.

Any person who is required to keep any record or make any report as a warehouse operator, dealer, buyer, trucker, or as a person engaged in the hauling, processing, or storage of tobacco, and who is engaged in more than one such business, shall keep such records as will enable such person to make separate reports for each such business in which such person is engaged to the same extent for each such business as if the person were engaged in no other business.

§ 723.413 Length of time records and reports are to be kept.

Records to be kept and copies of the reports required to be made by any person under this subpart shall be on a marketing year basis and shall be retained for 3 years after the end of the marketing year. Records shall be kept for such longer period of time as may be requested in writing by the State ASCS executive director, or the Director.

§ 723.414 Failure to keep records and make reports or making false report or record.

(a) (1) *Failure to keep records and make reports.* Under the provisions of section 373(a) of the Act, any warehouse operator, processor, buyer, dealer, trucker, or person engaged in the business of sorting, redrying, stemming, packing, or otherwise processing tobacco who fails to make any report or keep any record as required, or who makes any false report or record, is guilty of a misdemeanor, and upon conviction shall be subject to a fine of not more than $500 for each offense. In addition, any tobacco warehouse operator, dealer, or buyer who fails, upon being requested to do so, to remedy a violation by submitting complete reports and keeping accurate records shall be subject to an additional fine, not to exceed $5,000.

(2) *Failure to obtain producer marketing card or sale memo.* The failure of any dealer or warehouse operator to obtain a:

(i) Producer's marketing card, MQ–76 and MQ–77, to identify a sale of producer tobacco, or

(ii) Dealer identification card, MQ–79–2, to cover a resale of tobacco, shall constitute a failure to make a report.

(b) *False representation-warehouse operators, dealers, and processors.* The monetary penalties described in this part are in addition to penalties prescribed by other criminal statutes including 18 U.S.C. 231 which provides for a fine of not more than $10,000 or imprisonment for not more than 5 years, or both, for a person convicted of knowingly and willingly committing such acts as making a false acreage report, altering a marketing card, falsely identifying tobacco or buying and selling unused "103 percent of quota poundage" on marketing cards.

§ 723.415 Examination of records and reports.

For the purpose of ascertaining the correctness of any report made or record kept, or of obtaining the information required to be furnished, in any report, but not so furnished, any warehouse operator, processor, dealer, buyer, trucker, or person engaged in the business of sorting, redrying, stemming, picking, or otherwise processing tobacco for producers, shall make available at one place for examination by representatives of the State ASCS executive director and by employees of the Office of Investigation and Office of Audit, and of the Tobacco and Peanuts Division of the Agricultural Stabilization and Conservation Service, U.S. Department of Agriculture upon written request by the State ASCS executive director, all such books, papers, records, lot tickets, tobacco sale bills, buyer adjustment invoices, accounts, canceled checks, check register, check stubs, correspondence, contracts, documents, warehouse bill-out invoices or daily summary journal sheet, the tissue copy of Form MQ–72–1, Report of Tobacco Auction Sale, journal of producer marketing cards retained at warehouse and memoranda as the State ASCS executive director has reason to believe are relevant and are within the control of such person.

§ 723.416 Information confidential.

All data reported to or acquired by the Secretary pursuant to the provisions of this subpart shall be kept confidential by all officers and employees of the U.S. Department of Agriculture, by all members of county and community committees, and all county ASCS office employees. Only such data so reported or acquired as the Deputy Administrator deems relevant shall be disclosed by them, and then only in a suit or administrative hearing under title III of the Act. The provisions of this section shall not be deemed to prohibit the issuance of general statements based upon the report of a number of parties which statements do not identify the information furnished by any person.

Signed in Washington, DC, on June 12, 1990.

Keith D. Bjerke,

Administrator, Agricultural Stabilization and Conservation Service.

[FR Doc. 90–14083 Filed 6–19–90; 8:45 am]

BILLING CODE 3410–05–M

Agricultural Marketing Service

7 CFR Part 946

[Docket No. FV–90–164]

Irish Potatoes Grown in Washington; Proposed Rule To Reduce Minimum Weight Requirement for Long Varieties

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This proposed rule would reduce the minimum weight requirement for long varieties of Washington potatoes from 5 ounces to 4 ounces during the July 15 through August 31 period each season. Potato varieties currently being grown for the early market are longer and slimmer than those previously grown for that market. These potatoes often have difficulty meeting the current minimum size requirement of 2⅛ inches in diameter or 5 ounces in weight. Reducing the minimum weight requirement would recognize the difference in shape of these newer varieties and enable handlers to market a larger portion of their crop in fresh outlets.

DATES: Comments must be received by July 2, 1990.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposal to: Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2525–S, Washington, DC 20090–6456. Three copies of all written material shall be submitted, and they will be made available for public inspection at the Office of the Docket Clerk during regular business hours. All comments should reference the docket number and the date and page number of this issue of the **Federal Register.**

FOR FURTHER INFORMATION CONTACT: Robert F. Matthews, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, Room 2525–S, Washington, DC 20090–6456, telephone (202) 447–2431.

SUPPLEMENTARY INFORMATION: This rule is proposed under Marketing Agreement No. 113 and Marketing Order No. 946 (7 CFR part 946) regulating the handling of Irish potatoes grown in Washington. The marketing agreement and order are authorized by the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), hereinafter referred to as the Act.

This rule has been reviewed by the Department in accordance with Departmental Regulation 1512–1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this proposal on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursunat to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentally small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 55 handlers of Washington potatoes subject to regulation under the marketing order and approximately 520 producers in the production area. The Small Business Administration [13 CFR 121.2] has defined small agricultural producers as those having annual receipts of less than $500,000, and small agricultural service firms are defined as those whose annual receipts are less than $3,500,000. The majority of handlers and producers of Washington potatoes may be classified as small entities.

In recent years, annual potato production in Washington has averaged about 64 million hundredweight. About 85 percent of the crop is processed, and the remaining 15 percent is marketed in fresh outlets. Fresh shipments are comprised mainly of Russet Burbanks, Norgold Russets and Norkotah Russets, all of which are categorized as long varieties. Russet Burbanks, which account for about 65 percent of total fresh shipments, are harvested in the fall, with shipments beginning in September and continuing through the following June or early July. The largest shipments of Norgold Russets, Norkotah Russets and other early varieties are in July, August and September.

Handling requirements for fresh shipments of Washington potatoes are specified in 7 CFR 946.336 (46 FR 39117, July 31, 1981, as amended at 54 FR 27864, July 3, 1989, and 54 FR 41586, October 11, 1989). All varieties are required to grade at least U.S. No. 2. Long varieties are required to meet a minimum size requirement of 2⅛ inch in diameter or 5

ounces in weight from July 15 through August 31 each season, and 2 inches in diameter or 4 ounces in weight during the rest of the season.

At its meeting on April 24, 1990, the State of Washington Potato Committee (committee), the agency responsible for local administration of the marketing order, recommended reducing the minimum weight requirement for long varieties from 5 ounces to 4 ounces during the period July 15 through August 31, when early crop shipments are made. This would result in the same minimum weight requirement being in effect throughout the season.

When the current size requirements for long varieties were first established, the Norgold Russet was the primary variety being grown for the early market (i.e., the months of July and August). This variety is more round and blocky in shape than the Russet Burbank, the primary variety grown for the later market, and a larger minimum size requirement was appropriate. Additionally, the larger size requirement during the early part of the season was supported as a means of increasing demand for Washington potatoes during the period and to ensure that the early varieties were not harvested and shipped before they were fully mature.

However, several newer varieties are now being grown for the early market, such as the Norkotah Russet and Hilite Russet. These varieties have a more elongated and slimmer shape than the Norgold Russet. The shape of these varieties is more comparable to that of the Russet Burbank variety. Therefore, the committee recommended that the long variety potatoes marketed during the July 15 to August 31 period be subject to the same minimum weight requirement as those marketed later in the season. However, the committee recommended retaining the 2⅛ inch minimum diameter requirement for long varieties marketed during the period July 15 through August 31 since a significant quantity of Norgold Russet potatoes are still being grown for the early market.

In recent years, other production areas have also started growing these new early season varieties and are now competing in the same markets as Washington potatoes. The committee recommended reducing the minimum weight requirement to help early season shippers meet competition from other producing areas without a general lowering of quality which would ultimately work against the Washington potato industry. This action would also make the minimum weight requirement of 4 ounces the same for all Washington potato shippers throughout the marketing season.

Therefore, it is proposed that § 946.336 (a)(2)(ii) be revised to reduce the minimum weight of long varieties of early season potatoes from 5 ounces to 4 ounces. A conforming change would be made in paragraph (a)(2)(iii) with respect to tolerances.

Based on the above, the Administrator of the AMS has determined that this action would not have a significant economic impact on a substantial number of small entities.

It is hereby found that a comment period of 10 days is appropriate in that (1) this proposal was discussed by the committee at a public meeting, (2) the early shipping season usually begins in early July and this change would affect early season shippers, and (3) the proposal relaxes a size requirement.

List of Subjects in 7 CFR Part 946

Marketing agreements, Potatoes, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, it is proposed that 7 CFR part 946 be amended as follows:

PART 946—IRISH POTATOES GROWN IN WASHINGTON

1. The authority citation for 7 CFR part 946 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

2. Part 946 is amended by revising paragraphs (a)(2) (ii) and (iii) as follows:

§ 946.336 Handling regulation.

* * * * *

(a) * * *

(2) * * *

(ii) *Long varieties*—All long varieties must be 2⅛ inches (54.0 m.m.) in minimum diameter or 4 ounces minimum weight * * *

(a)(2)(iii) *Tolerances*—The tolerances for size contained in the U.S. Standards for Grades of Potatoes shall apply, except that for long varieties of potatoes packaged in other than 50-pound cartons and which are packed to meet a minimum size and weight of 2⅛ inches or 4 ounces, a 3 percent tolerance for undersize shall apply.

* * * * *

Dated: June 14, 1990.

Robert C. Keeney,

Deputy, Director, Fruit and Vegetable Division.

[FR Doc. 90–14207 Filed 6–19–90; 8:45 am]

BILLING CODE 3410–02–M

Food Safety and Inspection Service

9 CFR Parts 308, 318, 320 and 381

[Docket Number 89–007C]

RIN 0583–AB14

Processing, Distribution, Storage, and Retail Handling of Ready-to-Eat, Uncured, Perishable Meat and Poultry Products Packaged in Sealed Containers; Correction

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Advance notice of proposed rulemaking; Correction.

SUMMARY: On May 14, 1990, the Food Safety and Inspection Service (FSIS) published an advance notice of proposed rulemaking (55 FR 19888) requesting comments, information, scientific data and recommendations on whether FSIS should propose new regulations governing ready-to-eat, uncured, perishable meat and poultry products packaged in a variety of sealed containers bearing a "Perishable, Keep-Refrigerated" or similar statement. While discussing recommendations made by the National Advisory Committee on Microbiological Criteria for Foods, one recommendation was miscited as referring only to "rigid metal or glass" containers. This notice corrects the cited recommendation to make clear that it refers to "containers traditionally used for the marketing of shelf stable foods," and is not limited to containers of rigid metal or glass.

FOR FURTHER INFORMATION CONTACT: Ralph Stafko, Director, Policy Office, Policy Evaluation and Planning Staff, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250; (202) 447–8168.

SUPPLEMENTARY INFORMATION: On May 14, 1990, FSIS published an advance notice of proposed rulemaking (55 FR 19888) soliciting comments, information, scientific data and recommendations concerning whether FSIS should propose new regulations governing ready-to-eat, uncured, perishable meat and poultry products packaged in a variety of sealed containers bearing a "Perishable, Keep Refrigerated" or similar statement. The National Advisory Committee on Microbiological Criteria for Foods in its final report made several recommendations concerning packaging systems, distribution, refrigeration equipment, labeling, education and research which were discussed in the advance notice. Among these was a recommendation that the use of containers traditionally used for the

marketing of shelf stable foods not be used for keep refrigerated products that are not shelf stable until appropriate controls are in place to avoid consumer confusion and the risk of temperature abuse of these products. This recommendation was incorrectly characterized in that FSIS defined these traditional containers as rigid metal or glass. The correct recommendation, which does not limit "containers traditionally used for maketing of shelf stable foods" to those of "rigid metal or glass, is set forth below.

Done at Washington, DC, on: June 14, 1990.

Lester M. Crawford,

Administrator, Food Safety and Inspection Service.

The following corrections are made in the FSIS Notice Processing, Distribution, Storage, and Retail Handling of Ready-to-Eat, Uncured, Perishable Meat and Poultry Products Packaged in Sealed Containers, FR 90–11142, published in the **Federal Register** on May 14, 1990 (55 FR 19888).

1. The first full sentence in the second column on page 19889 which reads "Along specific recommendations of interest was the recommendation that the temperature be maintained at 40 °F. or lower during distribution, storage and handling of the products from the processing establishment to the retail sales outlet to assure the safety of the products, and the recommendation that the use of rigid metal or glass containers for such products be prohibited because there is a potential that consumers may confuse these products with shelf-stable products which are usually packaged in metal or glass containers." The sentence is revised to read as follows:

"Among specific recommendations of interest was the recommendation that the temperature be maintained at 40 °F. or lower during distribution, storage and handling of the products from the processing establishment to the retail sales outlet to assure the safety of the products, and the recommendation that the use of containers which have been traditionally used for the marketing of shelf stable foods not be use for keep refrigerated products until such time as safeguards are in place to avoid consumer confusion and the risk of temperature abuse."

2. In the third column near the bottom on page 19889, item e., is corrected to read as follows

"e. Need to regulate the kind of container used for these products, including whether to prohibit the use of containers traditionally used for the marketing of shelf stable foods."

* * * * *

[FR Doc. 90–14144 Filed 6–19–90; 8:45 am]

BILLING CODE 3410-DM-M

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 916

Kansas Permanent Regulatory Program and Abandoned Mine Land Reclamation Plan Submission

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Proposed rule; public comment period and opportunity for public hearing on proposed amendment.

SUMMARY: OSM is announcing receipt of a proposed amendment to the Kansas permanent regulatory program (hereinafter, the "Kansas program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). The proposed amendment pertains to revegetation success guidelines. The amendment is intended to revise the State program to be consistent with the corresponding Federal standards.

This notice sets forth the times and locations that the Kansas program and proposed amendment to that program are available for public inspection, the comment period during which interested persons may submit written comments on the proposed amendment, and procedures that will be followed regarding the public hearing, if one is requested.

DATES: Written comments must be received by 4 p.m., c.d.t. July 20, 1990. If requested, a public hearing on the proposed amendment will be held on July 16, 1990. Requests to present oral testimony at the hearing must be received by 4 p.m., c.d.t. on July 5, 1990.

ADDRESSES: Written comments should be mailed or hand delivered to Jerry R. Ennis at the address listed below.

Copies of the Kansas program, the proposed amendment, and all written comments received in response to this notice will be available for public review at the addresses listed below during normal business hours, Monday through Friday, excluding holidays. Each requester may receive one free copy of the proposed amendment by contacting OSM's Kansas City Field Office.

Jerry R. Ennis, Director, Kansas City Field Office, Office of Surface Mining Reclamation and Enforcement, 1103 Grand Avenue, room 502, Kansas City, MO 64106, Telephone: (816) 374–6405.

Kansas Department of Health and Environment, Surface Mining Section, Shirk Hall, 4th Floor, 1501 S. Joplin, P.O. Box 1418, Pittsburg, KS 66762, Telephone: (316) 231–8615.

FOR FURTHER INFORMATION CONTACT: Jerry R. Ennis, Director, Kansas City Field Office (816) 374–6405.

SUPPLEMENTARY INFORMATION:

I. Background on the Kansas Program

On January 21, 1981, the Secretary of Interior conditionally approved the Kansas program. General background information on the Kansas program, including the Secretary's findings, the disposition of comments, and the conditions of approval of the Kansas program can be found in the January 21, 1981, **Federal Register** (46 FR 5892). Subsequent actions concerning Kansas' program and program amendments can be found at 30 CFR 916.12, 916.15, and 916.16.

II. Proposed Amendment

By letter dated June 8, 1990, (Administrative Record No. KS–468) Kansas submitted a proposed amendment to its program pursuant to SMCRA. Kansas submitted the proposed amendment in response to a September 8, 1989, letter from OSM citing deficiencies in an amendment submitted June 29, 1989.

Kansas is proposing to adopt guidelines on the methods for determination of revegetation success prior to phase III bond release as required by 30 CFR 816.116(a)(1) and 817.116(a)(1).

III. Public Comment Procedures

In accordance with the provisions of 30 CFR 732.17(h), OSM is now seeking comment on whether the proposed amendment satisfies the applicable program approval criteria of 30 CFR 732.15. If the amendment is deemed adequate, it will become part of the Kansas progam.

Written Comments

Written comments should be specific, pertain only to the issue proposed in this rulemaking, and include explanations in support of the commenter's recommendations. Comments received after the time indicated under "**DATES**" or at locations other than the Kansas City Field Office will not necessarily be considered in the final rulemaking or included in the administrative record.

Public Hearing

Persons wishing to testify at the public hearing should contact the person listed under "**FOR FURTHER INFORMATION CONTACT**" by 4 p.m., c.d.t. July 5, 1990. The location and time of the hearing will be arranged with those persons requesting the hearing. If no one requests an opportunity to testify at a public hearing, the hearing will not be held.

Filing of a written statement at the time of the hearing is requested as it will greatly assist the transcriber. Submission of written statements in advance of the hearing will allow OSM officials to prepare adequate responses and appropriate questions.

The public hearing will continue on the specified date until all persons scheduled to comment have been heard. Persons in the audience who have not been scheduled to testify, and who wish to do so, will be heard following those who have been scheduled. The hearing will end after all persons scheduled to testify and persons present in the audience who wish to testify have been heard.

Public Meeting

If only one person requests an opportunity to testify at a hearing, a public meeting, rather than a public hearing, may be held. Persons wishing to meet with OSM representatives to discuss the proposed amendment may request a meeting at the OSM office listed under "**FOR FURTHER INFORMATION CONTACT.**" All such meetings will be open to the public and, if possible, notices of meetings will be posted at the locations listed under "**ADDRESSES.**" A written summary of each meeting will be made a part of the administrative record.

List of Subjects in 30 CFR Part 916

Intergovernmental relations, Surface mining, Underground mining.

Dated: June 13, 1990.

Raymond L. Lowrie,

Assistant Director, Western Field Operations.

[FR Doc. 90-14235 Filed 6-19-90; 8:45 am]

BILLING CODE 4310-05-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[PP 8E3686, 9E3768/P505; FRL-3690-2]

Pesticide Tolerances for Oryzalin

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: This document proposes that tolerances be established for residues of the herbicide oryzalin in or on the raw agricultural commodities green coffee beans and papayas. The proposed regulation to establish maximum permissible levels for residues of the herbicide in or on the commodities was requested by the Interregional Research Project No. 4.

DATES: Written comments, identified by the document control number [PP 8E3686, 9E3768/P505], must be received on or before July 20, 1990.

ADDRESSES: By mail, submit comments to: Public Information Branch, Field Operations Division (H7506), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., Sw., Washington, DC 20460. In person, deliver comments to: Rm. 246, CM #2, 1921 Jefferson Davis Highway, Arlington, VA 22202.

Information submitted as a comment concerning this document may be claimed confidential by marking any part or all of that information as "Confidential Business Information" (CBI). Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2. A copy of the comment that does not contain CBI must be submitted for inclusion in the public record. Information not marked confidential may be disclosed publicly by EPA without prior notice to the submitter. All written comments will be available for public inspection in Rm. 246 at the address given above from 8 a.m. to 4 p.m., Monday through Friday, excluding legal holidays.

FOR FURTHER INFORMATION CONTACT: By mail: Hoyt L. Jamerson, Emergency Response and Minor Use Section (H7505C), Registration Support Branch, Registration Division (H-7505C), Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 726, CM #2, 1921 Jefferson Davis Hwy., Arlington, VA 22202, 703-557-2310.

SUPPLEMENTARY INFORMATION: The Interregional Research Project No. 4 (IR-4), New Jersey Agricultural Experiment Station, P.O. Box 231, Rutgers University, New Brunswick, NJ 08903, has submitted pesticide petitions (PP) 8E3686 and 9E3768 to EPA on behalf of Dr. Robert H. Kupelian, National Director, IR-4 Project, and the Agricultural Experiment Station of Hawaii.

This petition requested that the Administrator, pursuant to section 408(e) of the Federal Food, Drug, and Cosmetic Act, propose the establishment of a tolerance for residues of the herbicide oryzalin (3,5-dinitroN^4,N^4-di(N-propyl)sulfanilamide) in or on the raw agricultural commodities green coffee beans and papayas at 0.05 part per million (ppm). The petitioner proposed that this use of oryzalin for coffee bean and papaya be limited to Hawaii based on the geographical representation of the residue data submitted. Additional residue data will be required to expand the area of usage. Persons seeking geographically broader registration should contact the Agency's Registration Division at the address provided above.

The data submitted in the petition and other relevant material have been evaluated. The pesticide is considered useful for the purpose for which the tolerances are sought. The toxicological data considered in support of the proposed tolerances include:

1. A 1-year dog feeding study with a no-observed-effect level (NOEL) of 5 milligrams(mg)/kilogram(kg)/day.

2. A 1-year mouse feeding study with a NOEL of 500 ppm (equivalent to 75 mg/kg). Dosage levels tested were 500, 1,350, and 3,650 ppm.

3. A 1-year rat feeding study with a NOEL fo 300 ppm (equivalent to 15 mg/kg/day).

4. A three-generation reproduction study in rats with a reproductive NOEL greater than 2,250 ppm (equivalent to 112.5 mg/kg/day, highest level tested) and a fetotoxic NOEL of 250 ppm (equivalent to 12.5 mg/kg/day, lowest level tested).

5. A rabbit teratology study with fetotoxic and maternal NOELs of 25 mg/kg/day and a developmental toxicity NOEL of greater than 125 mg/kg/day (highest level tested).

6. Two rat teratology studies: one with a NOEL greater than 2,250 ppm (equivalent to 112.5 mg/kg/day, highest level tested), and one with a NOEL greater than 225 mg/kg/day (equivalent to 4,500 ppm, highest level tested).

7. A battery of mutagenicity tests were all negative under conditions of the tests and include: an unscheduled DNA synthesis in rat hepatocytes; two dominant lethal assays in rats; and an Ames test (with and without S9 activation) at up to 300 micorgrams per plate. A chromatid exchange assay in Chinese hamster bone marrow was negative orally, and positive intraperitoneally.

8. A 2-year oncogenicity study in mice with a systemic NOEL of 500 ppm and no carcinogenic effects observed under the conditions of the study at dosage

levels of 0, 500, 1,350 and 3,650 ppm (equivalent to 0, 75, 202.5, and 547.5 mg/kg/day).

9. A 2-year rat feeding/oncogenicity study with a systemic NOEL of 300 ppm (equivalent to 15 mg/kg/day).

The rat chronic feeding/oncogenicity study demonstrated a dose-related reduction in survival and tumors of the thyroid gland, skin, and mammary gland at the 2,700 ppm level, which exceeded the maximum tolerated dose (MTD); some of the tumors (skin and mammary gland) occurred at the 900-ppm level which did not exceed the MTD. There were also mammary gland tumors at the 300-ppm level. The Agency concluded that there is limited evidence of carcinogenicity for oryzalin in male and female rats. Oryzalin has been classified as a Group C Carcinogen (a possible human carcinogen). This classification is based on the fact that oryzalin did not produce tumors in more than one species or strain, did not produce tumors in multiple experiments, nor produce tumors to an unusual degeree with regard to incidence, tumor site or type, or age of animal at onset. In addition, short-term tests for mutagenicity were negative.

A carcinogenic risk assessment for oryzalin has been completed by the Agency based on the available information. The potential carcinogenic risk to the general population from dietary exposure resulting from existing uses of oryzalin is calculated to be 2×10^{-6}. The dietary risk assessment is based on a potency estimator (Q^*) of 3.4×10^{-2} $(mg/kg/day)^{-1}$ and dietary exposure at 0.000057 mg/kg/day. The carcinogenic risk from dietary exposure to residues of oryzalin is expected to be less than calculated since information was not available to assume less than 100 percent treatment of all but eight commodities with established tolerances for oryzalin. In addition, tolerance levels were used to estimate residue levels in the raw agricultural commodities.

The proposed use on coffee will contribute a negligible incremental increase in risk which is estimated at 2.0×10^{-7} for the subgroup of the population which reports the highest coffee consumption (females, 13 years and older, coffee drinkers only). The carcinogenic risk estimate for coffee consumption is based on the consumption of approximately 2 cups of coffee per day. The consumption of larger amounts of coffee by some individuals is likely to pose a negligible incremental risk. The proposed use on papayas will contribute a negligible incremental increase of 10^{-8} to the carcinogenic risk estimate for oryzalin.

The nature of the residue is adequately understood, and an adequate analytical method, gas chromatography using an electron-capture detector, is available for enforcement purposes. An analytical method for enforcing this tolerance has been published in the *Pesticide Analytical Manual* (PAM), Vol. II. No secondary residues in meat, milk, poultry, or eggs are expected since coffee beans are not considered a livestock feed commodity. There are currently no actions pending against the continued registration of this chemical.

Based upon the above information considered by the Agency, the tolerance established by amending 40 CFR 180.304 would protect the public health. Therefore, it is proposed that the tolerance be established as set forth below.

Any person who has registered or submitted an application for registration of a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, that contains these ingredients may request within 30 days after publication of this document in the **Federal Register** that this rulemaking proposal be referred to an Advisory Committee in accordance with section 408(e) of the Federal Food, Drug, and Cosmetic Act.

Interested persons are invited to submit written comments on the proposed regulation. Comments must bear a notation indicating both the subject and the petition and document control number, [PP 8E3686, 9E3768/P505]. All written comments filed in response to this proposal will be available for inspection in the Registration Support Branch at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Pursuant to the requirements of the Regulatory Flexibility Act (Pub. L. 96-354, 94 Stat. 1164, 5 U.S.C. 601-612), the Administrator has determined that regulations establishing new tolerances or raising tolerance levels or establishing exemptions from tolerance requirements do not have a significant economic impact on a substantial number of small entities. A certification statement to this effect was published in the **Federal Register** of May 4, 1981 (46 FR 24950).

List of Subjects in 40 CFR Part 180

Administrative practice and procedure, Agricultural commodities, Pesticides and pests.

Dated: June 7, 1990.

Anne E. Lindsay,

Director, Registration Division, Office of Pesticide Programs.

Therefore, it is proposed that 40 CFR part 180 be amended as follows:

PART 180—[AMENDED]

1. The authority citation for part 180 continues to read as follows:

Authority: 21 U.S.C. 346a and 371.

2. Section 180.304 is amended by designating the current paragraph and list of tolerances as paragraph (a) and by adding new paragraph (b), to read as follows:

§ 180.304 Oryzalin; tolerances for residues.

* * * * *

(b) Tolerances with regional registration, as defined in § 180.1(n), are established for residues of oryzalin (3,5-dinitro-N^4,N^4-di(N-propyl)sulfanilamide) in or on the raw agricultural commodities as follows:

Commodities	Parts per million
Coffee beans, green	0.05
Papayas	0.05

[FR Doc. 90-14038 Filed 6-19-90; 8:45 am]
BILLING CODE 6560-50-D

GENERAL SERVICES ADMINISTRATION

48 CFR 516 and 552

[GSAR Notice No. 5-301]

General Services Administration Acquisition Regulation; Indefinite-Delivery Contracts

AGENCY: Office of Acquisition Policy, GSA.

ACTION: Proposed rule.

SUMMARY: This notice invites written comments on a proposed change to the General Services Administration Acquisition Regulation (GSAR) that would add section 516.505 to prescribe the Placement of Orders clause with two alternates for use by the Federal Supply Service in its Stock and Special Order Program and its Schedule Program; and section 552.216–XX to provide the text

for the Placement of Orders clause and two alternates identifying the activity or activities authorized to place delivery orders under the resulting contract and the procedures for issuing orders by Electronic Data Interchange, if mutually agreeable to the contracting agency and the contractor.

DATES: Comments are due in writing on or before July 20, 1990.

ADDRESSES: Comments should be addressed to Ms. Marjorie Ashby, Office of GSA Acquisition Policy (VP), 18th & F Streets, NW., room 4026, Washington, DC 20405.

FOR FURTHER INFORMATION CONTACT: Paul L. Linfeild, Office of GSA Acquisition Policy, (202) 501–1224.

SUPPLEMENTARY INFORMATION: The Director, Office of Management and Budget (OMB), by memorandum dated December 14, 1984, exempted certain agency procurement regulations from Executive Order 12291. This exemption applies to this proposed rule. Pursuant to the Regulatory Flexibility Act (5 U.S.C. 601 et seq.), the GSA certifies that the rule will not have a significant impact on a substantial number of small entities, since the issuance of electronically submitted orders must be agreeable to the contractor. This rule does not contain information collection requirement that require the approval of OMB under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501).

List of Subjects in 48 CFR Parts 516 and 552

Government procurement.

It is proposed that 48 CFR parts 516 and 552 be amended as follows:

1. The authority citation for 48 CFR parts 516 and 552 continues to read as follows:

Authority: 40 U.S.C. 486(c).

PART 516—TYPE OF CONTRACTS

2. Subpart 516.5 is added to read as follows:

Subpart 516.5—Indefinite-Delivery Contracts

516.505 Contract clauses.

The contracting officer shall insert the clause at 552.216–XX, Placement of Orders, in solicitations and contracts for Stock or Special Order Program items when the contract authorizes activities other than GSA to issue delivery orders. If GSA alone will issue delivery orders, the contracting officer shall use the clause at 552.216–XX with its Alternate I. If a Federal Supply Schedule contract (single or multiple award) is contemplated, the contracting officer shall use the clause at 552.215–XX with its Alternate II.

PART 552—SOLICITATION PROVISIONS AND CONTRACT CLAUSES

3. Section 552.216–XX is added to read as follows:

552.216–XX Placement of Orders.

As prescribed in 516.505, insert the following clause:

Placement of Orders (XXX 1990)

(a) Orders will be placed by:
[Contracting Officer insert names of Federal agencies]

(b) Orders may be issued either in hard copy or, when mutually agreeable to the contracting agency and the Contractor, electronically by using American National Standards Institute (ANSI) X12 Standard for Electronic Data Interchange (EDI) procedures.

(c) When EDI procedures are to be used to place orders, the Contractor shall enter into a separate Trading Partner Agreement (TPA) with each Federal activity placing orders electronically. The TPA shall identify, among other things, the third party provider(s) through which electronic orders are placed, the transaction sets used, security procedures, and guidelines for implementation.

(d) The Contractor shall be responsible for providing its own hardware and software necessary to transmit and receive data electronically under the framework of the TPA. Additionally, each party to the TPA shall be responsible for the costs associated with its use of third party provider services.

(e) Nothing in the TPA will invalidate any part of this contract between the Contractor and the General Services Administration. All terms and conditions that would otherwise be applicable to a paper delivery order shall apply to the electronic order.

(f) The basic content and format of the TPA will be provided by: General Services Administration, Systems Management and Analysis Division (FCS), Washington, DC 20406, Telephone: [Contracting Officer insert, FAX: appropriate telephone numbers].

(End of Clause)

Alternate I (XXX 1990). As prescribed in 516.505, substitute the following paragraphs (a), (b), and (c) for paragraphs (a), (b), and (c) of the basic clause:

(a) All orders under this contract will be placed by the General Services Administration (GSA). The Contractor is not authorized to accept orders from any other activity. Violation may result in termination of the contract pursuant to the Default clause of this contract.

(b) Orders may be issued either in hard copy, or when mutually agreeable to GSA and the Contractor, electronically by using American National Standards Institute (ANSI) X12 Standard for Electronic Data Interchange (EDI).

(c) When EDI procedures are to be used to place orders, the Contractor shall enter into a Trading Partner Agreement (TPA) with GSA. The TPA shall identify, among other things, the third party provider(s) through which electronic orders are placed, the transaction sets used, security procedures, and guidelines for implementation.

Alternate II (XXX 1990). As prescribed in § 516.505, substitute the following paragraph (a) for paragraph (a) of the basic clause:

(a) Delivery orders under the resulting contract may be issued by either the using Federal agencies or GSA.

Dated: June 6, 1990.

Richard H. Hopf, III,

Associate Administrator for Acquisition Policy.

[FR Doc. 90–14232 Filed 6–19–90; 8:45 am]

BILLING CODE 6820–61–M

Notices

Federal Register
Vol. 55, No. 119
Wednesday, June 20, 1990

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

DEPARTMENT OF AGRICULTURE

Agricultural Research Service

Intent To Grant an Exclusive License

AGENCY: Agricultural Research Service, USDA.

ACTION: Notice of intent.

SUMMARY: Notice is hereby given that the U.S. Department of Agriculture, Agricultural Research Service, intends to grant an exclusive license to Embrex, Inc., Morrisville, North Carolina on U.S. Patent Application Serial No. 07/362,635, "Introduction of Bacteria *In Ovo*, filed June 5, 1989.

DATES: August 20, 1990.

ADDRESSES: Send comments to: USDA–ARS–Office of Cooperative Interactions, Beltsville Agricultural Research Center, Baltimore Boulevard, Building 005, Room 401, BARC–W, Beltsville, Maryland 20705.

FOR FURTHER INFORMATION CONTACT: M. Ann Whitehead of the Office of Cooperative Interactions at the Beltsville address given above; telephone: 301/344–2786, (FTS) 344–2786.

SUPPLEMENTARY INFORMATION: The USDA–ARS intends to grant to Embrex, Inc., an exclusive license to practice the invention disclosed in U.S. Patent Application Serial No. 07/362,635, "Introduction of Bacteria *In Ovo*," filed June 5, 1989. Notice of Availability was given in the **Federal Register** on July 26, 1989. The patent rights in this invention have been assigned to the United States of America as represented by the Secretary of Agriculture. It is in the public interest to so license this invention as Embrex, Inc., has submitted a complete and sufficient application for a license and has entered into a Cooperative Reseach and Development Agreement with the Agricultural Research Service providing for further development of the invention. The prospective exclusive license will be royalty-bearing and will comply with the terms and conditions of 35 U.S.C. 209 and 37 CFR 404.7 and will conform to the intent of 15 U.S.C. 3710a. The prospective exclusive license may be granted unless, within sixty days from the date of this published Notice, ARS receives written evidence and argument which establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR 404.7.

William H. Tallent,
Assistant Administrator.

[FR Doc 90–14208 Filed 6–19–90; 8:45 am]
BILLING CODE 3410–34–M

Animal and Plant Health Inspection Service

[Docket No. 90–080]

Request for Expedited Processing; Agency Information Collection Under OMB Review

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We have submitted four proposed information collection requirements—the collection of information for issuance of a Permit for Movement of Restricted Poultry and Poultry Products, the Egg Trace Investigation Report, the On Farm Epidemiology Report, and the Specimen Submission Form—to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act and regulations issued thereunder. The purpose of this information collection material is to provide us with information concerning poultry flocks that will be tested by the *Salmonella enteritidis* Program Task Force. The information we collect will help us to estimate the levels of materials, services, and training we will need to provide for *Salmonella enteritidis* Program Task Force activities and to conduct activities required under the *Salmonella enteritidis* regulations.

DATES: We have requested an expedited review of this submission under the Paperwork Reduction Act in accordance with 5 CFR 1320.18, to be completed by June 29, 1990.

ADDRESSES: Send written comments to the Office of Information and Regulatory Affairs, OMB, Attention: Desk Officer for APHIS, Washington, DC 20503. You should submit a duplicate copy of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 866, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket Number 90–080. Comments received may be inspected at USDA, room 1141, South Building, 14th and Independence Ave., SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. M.A. Mixson, Chief Staff Veterinarian, Emergency Programs Staff, VS, APHIS, USDA, room 746, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, 301–436–8073.

SUPPLEMENTARY INFORMATION:

Background

Salmonella enteritidis (SE), a communicable disease of poultry, is a present and expanding cause of economic concern for the United States egg-type chicken industry, and is a serious public health concern. Strains of SE are endemic in egg producing and egg-type breeding flocks in northeastern and mid-Atlantic States. However, the incidence of SE has been increasing and spreading to many States. These developments prompted the United States Department of Agriculture to declare an emergency on February 1, 1990, and to take immediate action to control the further spread of SE in poultry flocks in the United States.

To this end, the SE Program Task Force (referred to below as the Task Force) was created to test certain egg-type poultry breeding and production flocks implicated as the source of Salmonellosis outbreaks in poultry or humans. The Task Force is also responsible for implementing the current SE regulations contained in 9 CFR parts 71 and 82 (referred to below as the SE regulations). The information collection material we are submitting to OMB for review and approval is urgently needed by the Task Force in order to carry out its responsibilities.

The Permit for Movement of Restricted Poultry and Poultry Products is used to control the interstate movement of such poultry and products from test flocks and infected flocks.

Information is collected either orally or in writing concerning the eligibility of restricted poultry and poultry products to move interstate from such flocks.

The Egg Trace Investigation Report would be used to collect information concerning where infected eggs originated. It would assist us in pinpointing the flock that produced the eggs.

The On Farm Epidemiology Report would be used to collect information concerning the health of a particular flock. It would assist us in determining the SE status of a flock, the testing procedures required for that flock, and whether the flock should be subject to egg tracing or other investigative procedures.

The Specimen Submission Form would be used to identify specimens, such as internal organs, collected from poultry during an investigation. The form is necessary to ensure that specimens are correctly identified by flock and flock owner.

All of the above information collection materials would help us to determine what additional resources are needed by the Task Force to carry out its mission. The need for this information is urgent, since States have started to test flocks for SE, and the demand for field and laboratory resources has increased. It is necessary to begin collecting this information as soon as possible in order to prevent further spread of SE in the egg-type chicken industry.

Therefore, we have requested the Office of Management and Budget to complete its Paperwork Reduction Act review of the information collection provisions on an expedited basis and provide us with its determination by June 29, 1990.

The collection of information for issuance of a Permit for Movement of Restricted Poultry and Poultry Products, the Egg Trace Investigation Report, the On Farm Epidemiology Report, and the Specimen Submission Form will be used to collect data on approximately 478 flocks of egg-type breeding or production chickens. The data will be collected by Veterinary Medical Officers of the Animal and Plant Health Inspection Service and by State representatives, who will obtain the necessary information from approximately 478 egg processors and owners, operators, or managers of egg-type poultry breeding or production flocks. Although these processors, owners, operators, or managers are considered the recordkeepers, we do not believe they will need to maintain any new records as a result of the reports and the form, since the information required is commonly used and recorded by these individuals for other business purposes.

An estimate of the total annual reporting and recordkeeping burden and the estimated average burden hours per response is given below.

Permit for Movement of Restricted Poultry and Poultry Products

Number of Respondents	520
Average Number of Responses per Respondent	80
Hours per Response	.25

Egg Trace Investigation Report

Number of Respondents	64
Average Number of Responses per Respondent	2
Hours per Response	1

On Farm Epidemiology Report

Number of Respondents	350
Average Number of Responses per Respondent	1
Hours per Response	2

Specimen Submission Form

Number of Respondents	7,500
Average Number of Responses per Respondent	6
Hours per Response	.25

Done in Washington, DC, this 15th day of June 1990.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 90-14277 Filed 6-19-90; 8:45 am]

BILLING CODE 3410-34-M

[Docket No. 90-91]

Availability of Environmental Assessment and Finding of No Significant Impact Relative to Issuance of a Permit To Field Test Genetically Engineered Clavibacter xyli subsp. cynodontis

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that an environmental assessment and finding of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to the issuance of a permit to Crop Genetics International Corporation to allow the field testing in Queen Annes County, Maryland, of *Clavibacter xyli* subsp. *cynodontis* genetically engineered to express a gene from *Bacillus thuringiensis* var. *kurstaki*, which encodes a delta-endotoxin protein that is lethal to the larvae of some lepidopteran insects. The assessment provides a basis for the conclusion that the field testing of these genetically engineered *Clavibacter xyli* subsp. *cynodontis* will not present a risk of the introduction or dissemination of a plant pest and will not have a significant impact on the quality of the human environment. Based on this finding of no significant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

ADDRESSES: Copies of the environmental assessment and finding of no significant impact are available for public inspection at Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Ellen Liberman, Biotechnologist, Biotechnology Permits, Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, room 846, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7612. For copies of the environmental assessment and finding of no significant impact, write Mr. Clayton Givens at this same address. The environmental assessment should be requested under permit number 90-016-01.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340 regulate the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms and products that are plant pests or that there is reason to believe are plant pests (regulated articles). A permit must be obtained before a regulated article can be introduced into the United States. The regulations set forth procedures for obtaining a limited permit for the importation or interstate movement of a regulated article and for obtaining a permit for the release into the environment of a regulated article. The Animal and Plant Health Inspection Service (APHIS) has stated that it would prepare an environmental assessment and, when necessary, an environmental impact statement before issuing a permit for the release into the environment of a regulated article (see 52 FR 22906).

The Crop Genetics International Corporation, of Hanover, Maryland, has submitted an application for a permit for release into the environment, to field test *Clavibacter xyli* subsp. *cynodontis* genetically engineered to express a gene from *Bacillus thuringiensis* var. *kurstaki*, which encodes a delta-endotoxin protein that is lethal to the larvae of some lepidopteran insects. The

field trial will take place in Queen Anne's County, Maryland.

In the course of reviewing the permit application, APHIS assessed the impact on the environment of releasing the *Clavibacter xyli* subsp. *cynodontis* under the conditions described in the Crop Genetics International Corporation application. APHIS concluded that the field testing will not present a risk of plant pest introduction or dissemination and will not have a significant impact on the quality of the human environment.

The environmental assessment and finding of no significant impact, which are based on data submitted by the Crop Genetics International Corporation, as well as a review of other relevant literature, provide the public with documentation of APHIS' review and analysis of the environmental impacts associated with conducting the field testing.

The facts supporting APHIS' finding of no significant impact are summarized below and are contained in the environmental assessment.

1. An insecticidal gene from *B. thuringiensis* var. *kurstaki* has been modified and inserted into the *C. xyli* subsp. *cynodontis* chromosome resulting in the biosynthesis of delta-endotoxin. Neither the delta-endotoxin gene nor its polypeptide product confers on the bacterium any plant pest characteristics.

2. The delta-endotoxin gene does not confer on the recombinant bacterium any measurable selective advantage over the no-recombinant bacterium in its ability to be dispersed or to become established in the environment.

3. The genetic alterations are not expected to enhance any plant pathogenic property of the recombinant bacterium as compared to the parental strain of C. *xyli* subsp. *cynodontis*. *C. xyli* subsp. *cynodontis* is already present in the State of Maryland where the test plot is located.

4. *C. xyli* subsp. *cynodontis* is transferred to other plants by mechanical means; e.g., cutting tools. Transfer to other plants will be minimized using field protocols which include tool disinfection and buffer zones. In addition, regular monitoring for the recombinant bacterium will ensure that if it spreads to plants at the edge of the test plots, it will be detected.

5. *C. xyli* subsp. *cynodontis* is an endophytic bacterium (a bacterium that lives only with a plant) which inhabits the vascular system of specific plants. Therefore, the ability to multiply outside a plant host species is limited and dissemination of the recombinant bacterium can only occur with susceptible plant species. Monitoring and trap plants should readily detect any dispersal by this means.

6. Monitoring for the persistence of the recombinant bacterium in plant debris will be carried out after harvest. All harvested seed will be buried or burned at the end of the experiment.

7. The endophytic-lifecycle of the bacterium makes it unlikely that horizontal gene transfer to other bacteria by known mechanisms, transduction, transformation, or conjugation will occur.

8. There were no listed threatened or endangered insects species (January 1, 1989, 50 CFR 17.11 and 17.12) present in the test site in Maryland, so the introduction of the recombinant bacterium poses no risk to these insects.

9. No human health risk is posed by the use of the recombinant strain of *C. xyli* subsp. *cynodontis*. The bacterium does not grow at human body temperature. The bacterium has been shown to be nonpathogenic and nontoxic in mammalian tests. In addition, all crops will be used for research purposes or destroyed so that there will be no dietary exposure to humans.

The environmental assessment and finding of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4331 *et seq.*), (2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500–1509). (3) USDA Regulations Implementing NEPA (7 CFR part 1b), and (4) APHIS Guidelines Implementing NEPA (44 FR 50381–50384, August 28, 1979, and 44 FR 51272–51274, August 31, 1979).

Done in Washington, DC, this 13th day of June 1990.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 90–14213 Filed 6–19–90; 8:45 am]

BILLING CODE 3410–34–M

[Docket No. 90–077]

Availability of Environmental Assessment and Finding of No Significant Impact Relative to Issuance of a Permit To Field Test Genetically Engineered Cotton Plants

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that an environmental assessment and finding of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to the issuance of a permit to the Monsanto Agricultural Company to allow the field testing in Baldwin County, Alabama; Pinal County, Arizona; Imperial County, California; Bossier Parish, Louisiana; Oktibbeha County, Mississippi; and Brazos and Hale Counties, Texas, of cotton plants genetically engineered to express a gene for a delta-endotoxin protein from *Bacillus thuringiensis* var. *kurstaki* that blocks the feeding of the larval stages of select lepidopteran insects. The assessment provides a basis for the conclusion that the field testing of these genetically engineered cotton plants will not present a risk of introduction or dissemination of a plant pest and will not have a significant impact on the quality of the human environment. Based on this finding of no signficant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

ADDRESSES: Copies of the environmental assessment and finding of no significant impact are available for public inspection at Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD, between 8 a.m and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Quentin B. Kubicek, Biotechnologist, Biotechnology Permits, Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, room 841, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (303) 436–7612. For copies of the environmental assessment and finding of no significant impact, write Mr. Clayton Givens at this same address. The environmental assessment should be requested under permit number 90–032–02.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340 regulate the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms and products that are plant pests or that there is reason to believe are plant pests (regulated articles). A permit must be obtained before a regulated article can be introduced into the United States. The regulations set forth procedures for obtaining a limited permit for the importation or interstate movement of a regulated article and for obtaining a permit for the release into the environment of a regulated article. The Animal and Plant Health Inspection

Service (APHIS) has stated that it would prepare an environmental assessment and, when necessary, an environmental impact statement before issuing a permit for the release into the environment of a regulated article (see 52 FR 22906).

The Monsanto Agricultural Company, of St. Louis, Missouri, has submitted an application for a permit for release into the environment, to field test cotton plants genetically engineered to express a gene for a delta-endotoxin protein from *Bacillus thuringiensis* var. *kurstaki* that blocks the feeding of the larval stages of select lepidopteran insects. The field trials will take place in Baldwin County, Alabama; Pinal County, Arizona; Imperial County, California; Bossier Parish, Louisiana; Oktibbeha County, Mississippi; and Brazos and Hale Counties, Texas.

In the course of reviewing the permit application, APHIS assessed the impact on the environment of releasing the cotton plants under the conditions described in the Monsanto Agricultural Company application. APHIS concluded that the field testing will not present a risk of plant pest introduction or dissemination and will not have a significant impact on the quality of the human environment.

The environmental assessment and finding of no signficant impact, which are based on data submitted by the Monsanto Agricultural Company, as well as a review of other relevant literature, provide the public with documentation of APHIS' review and analysis of the environmental impacts associated with conducting the field testing.

The facts supporting APHIS' finding of no significant impact are summarized below and are contained in the environmental assessment.

1. A gene encoding for the delta-endotoxin protein which is toxic to select lepidopteran insects has been inserted into a cotton chromosome. In nature, chromosomal genetic material can only be transferred to another sexually compatible plant by cross-pollination. In this field test, the introduced gene cannot spread to another sexually compatible plant by cross-pollination because the field test plot is located at a sufficient distance from any sexually compatible cotton plant.

2. Neither the gene which encodes for the delta-endotoxin nor its gene product, confers on cotton any plant pest characteristic. Traits that lead to weediness are polygenic and cannot be conferred by adding a single gene.

3. The delta-endotoxon gene does not provide the transformed cotton plants with any measurable selective advantages over nontransferred cotton plants in the ability to be disseminated or to become established in the environment.

4. Select noncoding regulatory regions derived from plant pests have been incorporated into the plant DNA but do not confer on cotton any plant pest characteristic.

5. The bacterium from which the delta-endotoxin gene is isolated is not a plant pest.

6. The vector used to transfer the genes to cotton plants has been evaluated for its use in this specific experiment and does not pose a plant pest risk in this experiment. The vector, although derived from a DNA sequence of a known plant pest, has been disarmed; that is, pathogenicity genes have been removed from the vector. The vector has been tested and shown to be nonpathogenic to any susceptible plant.

7. The vector agent, the bacterium that was used to deliver the vector DNA and the genes into the plant cell, has been shown to be eliminated and no longer associated with any transformed cotton plant.

8. Horizontal movement of the introduced genes is not possible. The vector acts by delivering the gene to the plant genome (i.e., chromosomal DNA). The vector does not survive in or on any plant.

9. The toxic polypeptide produced by the engineered gene is called delta-endotoxin. Upon ingestion, the toxin kills only lepidopteran insects. Delta-endotoxin is not toxic to other insects, birds, fish or mammals. Because of its safety, its topical application on vegetable crops is permitted up to harvest date.

The environmental assessment and finding of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4331 *et seq.*), (2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500–1509), (3) USDA Regulations Implementating NEPA (7 CFR part 1b), and (4) APHIS Guidelines Implementing NEPA (44 FR 50381–50384, August 28, 1979, and 44 FR 51272–51274, August 31, 1979).

Done in Washington, DC, this 13th day of June 1990.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 90–14211 Filed 6–19–90; 8:45 am]

BILLING CODE 3410–34–M

[Docket 90–095]

Availability of Environmental Assessment and Finding of No Significant Impact Relative to Issuance of a Permit To Field Test Genetically Engineered Cotton Plants

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that an environmental assessment and finding of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to the issuance of a permit to the Monsanto Agricultural Company to allow the field testing in Baldwin County, Alabama, of cotton plants genetically engineered to express a gene encoding a modified 5-enolpyruvyl-3-phosphoshikimate synthase which shows reduced sensitivity to the herbicide glyphosate and/or a gene which encodes an enzyme that acts on glyphosate. The assessment provides a basis for the conclusion that the field testing of these genetically engineered cotton plants will not present a risk of introduction or dissemination of a plant pest and will not have a significant impact on the quality of the human environment. Based on this finding of no significant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

ADDRESSES: Copies of the environmental assessment and finding of no significant impact are available for public inspection at Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. James White, Biotechnologist, Biotechnology Permits, Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, room 844, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–7612. For copies of the environmental assessment and finding of no significant impact, write Mr. Clayton Givens at this same address. The environmental assessment should be requested under permit number 90–023–01.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340 regulate the introduction (importation, interstate movement, and release into the

environment) of genetically engineered organisms and products that are plant pests or that there is reason to believe are plant pests (regulated articles). A permit must be obtained before a regulated article can be introduced into the United States. The regulations set forth procedures for obtaining a limited permit for the importation of interstate movement of a regulated article and for obtaining a permit for the release into the environment of a regulated article. The Animal and Plant Health Inspection Service (APHIS) has stated that it would prepare an environmental assessment and, when necessary, an environmental impact statement before issuing a permit for the release into the environment of a regulated article (see 52 FR 22906).

The Monsanto Agricultural Company, of St. Louis, Missouri, has submitted an application for a permit for release into the environment, to field test cotton plants genetically engineered to express a gene encoding a modified 5-enolpyruvyl-3-phosphoshikimate synthase which shows reduced sensitivity to the herbicide glyphosate and/or a gene which encodes an enzyme that acts on glyphosate. The field trial will take place in Benton County, Washington.

In the course of reviewing the permit application, APHIS assessed the impact on the environment of releasing the cotton plants under the conditions described in the Monsanto Agricultural Company application. APHIS concluded that the field testing will not present a risk of plant pest introduction or dissemination and will not have a significant impact on the quality of the human environment.

The environmental assessment and finding of no significant impact, which are based on data submitted by Monsanto Agricultural Company, as well as a review of other relevant literature, provide the health with documentation of APHIS' review and analysis of the environmental impacts associated with conducting the field testing.

The facts supporting APHIS' finding of no significant impact are summarized below and are contained in the environmental assessment.

1. A gene encoding a modified 5-enolpyruvyl-3-phosphoshikimate synthase which shows reduced sensitivity to the herbicide glyphosate and/or a gene which encodes glyphosate tolerance has been inserted into the cotton chromosome. In nature, chromosomal genetic material can only be transferred to other sexually compatible plants by cross-pollination. In this field trial, the introduced gene cannot spread to other plants by cross-pollination because the field test plot is a sufficient distance from any sexually compatible plants with which it might cross-pollinate.

2. Neither the recombinant genes themselves nor their protein products, confer on cotton any plant pest characteristics. Traits that lead to weediness in plants are polygenic traits and cannot be conferred by adding a single gene.

3. The plants from which the 5-enolpyruvyl-3-phosphoshikimate synthase gene were isolated are not plant pests. The microorganism from which the gene was isolated which encodes glyphosate tolerance is not a plant gene.

4. Select noncoding regulatory regions derived from plant pests have been incorporated into the plant DNA but do not confer on cotton any plant pest characteristics.

5. Neither of the recombinant genes provide the transformed cotton plants with any measurable selective advantage over nontransformed cotton in the ability to be disseminated or to become established in the environment.

6. The vector used to transfer the genes to cotton plants has been evaluated for its use in this specific experiment and does not pose a plant pet risk in this experiment. The vector, although derived from a DNA sequence with known plant pest potential, has been disarmed; that is, genes that are necessary for producing plant disease have been removed from the vector. The vector has been tested and shown to be nonpathogenic to susceptible plants.

7. The vector agent, the bacterium that was used to deliver the vector DNA and the genes into the plant cell, has been shown to be eliminated and no longer associated with the transformed cotton plants.

8. Horizontal movement of the introduced genes is not possible. The vector acts by delivering the gene to the plant genome (i.e., chromosomal DNA). The vector does not survive in the plants.

9. Glyphosate is one of the new herbicides that is rapidly degraded in the environment. It has been shown to be less toxic to animals than many herbicides commonly used.

10. The field test site is small (about 3 acres) and physically isolated by a surrounding area of cultivated land.

The environmental assessment and finding of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4331 *et seq.*), (2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR Parts 1500–1509), (3) USDA Regulations Implementing NEPA (7 CFR part 1b), and (4) APHIS Guidelines Implementing NEPA (44 FR 50381–50384, August 28, 1979, and 44 FR 51272–51274, August 31, 1979).

Done in Washington, DC, this 13th day of June 1990.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc 90–14212 Filed 6–19–90; 8:45 am]

BILLING CODE 3410-34-M

[Docket No. 90–089]

Availability of Environmental Assessment and Finding of No Significant Impact Relative to Issuance of a Permit To Field Test Genetically Engineered Tomato Plants

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that an environmental assessment and finding of no significant impact have been prepared by the Animal and Plant Health Inspection Service relative to the issuance of a permit to the Monsanto Agricultural Company to allow the field testing to Hughson, California, of tomato plants genetically engineered to express a gene from *Bacillus thuringiensis* var. *kurstaki*, which encodes a delta-endotoxin protein that is toxic to the larvae of some lepidopteran insects. The assessment provides a basis for the conclusion that the field testing of these genetically engineered tomato plants will not present a risk of introduction or dissemination of a plant pest and will not have a significant impact on the quality of the human environment. Based on this finding of no significant impact, the Animal and Plant Health Inspection Service has determined that an environmental impact statement need not be prepared.

ADDRESSES: Copies of the environmental assessment and finding of no significant impact are available for public inspection at Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays.

FOR FURTHER INFORMATION CONTACT: Dr. Quentin B. Kubicek, Biotechnologist, Biotechnology Permits, Biotechnology

Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, room 841, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–7612. For copies of the environmental assessment and finding of no significant impact, write Mr. Clayton Givens at this same address. The environmental assessement should be requested under permit number 90–038–02. Permit number 90–038–02 is a renewal of permit number 89–030–02, issued April 28, 1989.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340 regulate the introduction (importation, interstate movement, and release into the environment) of genetically engineered organisms and products that are plant pests or that there is reason to believe are plant pests (regulated articles). A permit must be obtained before a regulated article can be introduced into the United States. The regulations set forth procedures for obtaining a limited permit for the importation or interstate movement of a regulated article and for obtaining a permit for the release into the environment of a regulated article. The Animal and Plant Health Inspection Service (APHIS) has stated that it would prepare an environmental assessment and, when necessary, an environmental impact statement before issuing a permit for the release into the environment of a regulated article (see 52 FR 22960).

The Monsanto Agricultural Company, of St. Louis, Missouri, has submitted an application for a permit for release into the environment, to field test tomato plants genetically engineered to express a gene from *Bacillus thuringiensis* var. *kurstaki*, which encodes a delta-endotoxin protein that is toxic to the larvae of some lepidopteran insects. The field trial will take place in Hughson County, California.

In the course of reviewing the permit application, APHIS assessed the impact on the environment or releasing the tomato plants under the conditions described in the Monsanto Agricultural Company application. APHIS concluded that the field testing will not present a risk of plant pest introduction or dissemination and will not have a significant impact on the quality of the human environment.

The environmental assessment and finding of no significant impact, which are based on data submitted by the Monsanto Agricultural Company, as well as a review of other relevant literature, provide the public with documentation of APHIS' review and analysis of the environmental impacts associated with conducting the field testing.

The facts supporting APHIS' finding of no significant impact are summarized below and are contained in the environmental assessment.

1. A gene from *B. thuringiensis* var. *kurstaki* HDI encoding the delta-endotoxin protein has been inserted into a tomato chromosome. The expression of this gene provides tolerance against the larvae of select lepidopteran insects. In nature, genetic material contained in a chromosome is generally transferred to another sexually compatible plant by cross-pollination. In this field trial, no introduced gene can spread to another plant by cross-pollination, because the field test plot is located at a sufficient distance from any sexually compatible plant with which these experimental tomato plants could cross-pollinate.

2. Neither the delta-endotoxin gene itself, nor its gene product confers on tomato any plant pest characteristic.

3. The bacterium from which the delta-endotoxin gene was isolated is not a plant pest and is widely distributed in the environment as a soil inhabitant.

4. The vector used to transfer the delta-endotoxin gene to tomato plant cells has been evaluated for its use in this specific experiment and does not pose a plant pest risk in this experiment. The vector, although derived from the DNA of a tumor inducing (Ti) plasmid with known plant pathogenic potential, has been disarmed; that is, genes that are necessary for pathogenicity have been removed from the vector. The vector has been tested and shown to be not pathogenic to any susceptible plant.

5. The vector agent *Agrobacterium tumefaciens*, a phytopathogenic bacterium, was used to deliver the vector DNA and the delta-endotoxin gene into tomato plant cells. The vector agent has been shown to be eliminated and no longer associated with any transformed tomato plant.

6. Horizontal movement or gene transfer of the delta-endotoxin gene is not possible. The vector acts by delivering and inserting the gene into a tomato chromosome (i.e., chromosomal DNA). The vector does not survive in or on any transformed tomato plant. No mechnism for horizontal movement is known to exist in nature to move an inserted gene from a chromosome of a transformed plant to any other organism.

7. The toxic polypeptide produced by the engineered gene is called delta-endotoxin. Upon ingestion, the toxin kills only the larvae of select lepidopteran insects. Delta-endotoxin is not toxic to other insects, wild or domestic birds, fish, or animals. Because of its safety, its topical application on crops is permitted up to the time of harvest.

8. The size of the field test plot is small (0.2 acre and a total of 600 transformed tomato plants) and will be located on a private research farm in a rural area. The field test plot will be located at least 30 feet from breeder or commercial tomato plants and is surrounded by other agronomic crops and orchards.

The environmental assessment and finding of no significant impact have been prepared in accordance with: (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4331 *et seq.*), (2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR parts 1500–1509), (3) USDA Regulations Implementing NEPA (7 CFR part lb), and (4) APHIS Guidelines Implementing NEPA (44 FR 50381–50384, August 28, 1979, and 44 FR 51272–51274, August 31, 1979).

Done in Washington, DC, this 13th day of June 1990.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 90–14214 Filed 6–19–90; 8:45 am]

BILLING CODE 3410–34–M

[Docket No. 90–067]

U.S. Veterinary Biological Product and Establishment Licenses Issued, Suspended, Revoked, or Terminated

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: The purpose of this notice is to advise the public of the issuance, suspension, revocation, or termination of veterinary biological product and establishment licenses by the Animal and Plant Health Inspection Service during the month of March 1990. These actions are taken in accordance with the regulations issued pursuant to the Virus-Serum-Toxin Act.

FOR FURTHER INFORMATION CONTACT. Joan Montgomery, Program Assistant, Veterinary Biologics, Biotechnology, Biologics, and Environmental Protection, Animal and Plant Health Inspection Service, U.S. Department of Agriculture, Room 838, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436–8674.

SUPPLEMENTARY INFORMATION: The regulations in 9 CFR part 102, "Licenses

For Biological Products," requires that every person who prepares certain biological products that are subject to the Virus-Serum Toxin Act (21 U.S.C. 151 *et seq.*) shall hold an unexpired, unsuspended, and unrevoked U.S. Veterinary Biological Product License. The regulations set forth the procedures for applying for a license, the criteria for determining whether a license shall be issued, and the form of the license.

Pursuant to these regulations, the Animal and Plant Health Inspection Service (APHIS) issued the following U.S. Veterinary Biological Product Licenses during the month of March 1990:

Product license code	Date issued	Product	Establishment	Establishment license No.
1051.11	03-14-90	Avian Encephalomyelitis Vaccine, Live Virus	Schering Corporation	165-A
1282.00	03-29-90	Bursal Disease-Marek's Disease Vaccine, Modified Live Virus, Live Turkey Herpesvirus, Cell Associated.	Immunogenetics, Inc.	196
13D8.30	03-23-90	Canine Distemper-Adenovirus Type 2-Parainfluenza-Parvovirus Vaccine, Modified Live Virus.	Rhone Merieux, Inc	298
1475.22	03-14-90	Encephalomyelitis Vaccine, Eastern and Western, Killed Virus	American Home Products Corporation	112
1599.21	03-20-90	Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine, Modified Live and Killed Virus.	American Home Products Corporation	112
1652.01	03-14-90	Marek's Disease Vaccine, Live Chicken and Turkey Herpesvirus	Tri Bio Laboratories, Inc	275
16G8.00	03-08-90	Marek's Disease Vaccine, Live Chicken and Turkey Herpesvirus	Solvay Animal Health, Inc	195
1751.00	03-09-90	Mycoplasma Gallisepticum Vaccine, Live Culture	Arko Laboratories, Ltd	337
1871.04	03-09-90	Pasteurella Multocida Vaccine, Avirulent Live Culture, Avian Isolate	Schering Corporation	165-A
18C5.00	03-02-90	Pacheco's Disease Vaccine, Killed Virus	Biomune, Incorporated	368
2672.00	03-16-90	Haemophilus Pleuropneumoniae-Streptococcus Suis Bacterin	Oxford Veterinary Laboratories, Inc	307
4435.20	03-09-90	Bovine Rhinotracheitis-Virus Diarrhea-Parainfluenza ^{3} Vaccine—Leptospira Canicola-Grippotyphosa-Hardjo-Icterohaemorrhagiae-Pomona Bacterin, Killed Virus.	Grand Laboratories, Inc	303
46J9.21	03-29-90	Canine Distemper-Adenovirus Type 2-Coronavirus-Parainfluenza-Parvovirus Vaccine-Leptospira Bacterine, Modified Live and Killed Virus.	American Home Products Corporation	112
4865.20	03-15-90	Encephalomyelitis Vaccine-Tetanus Toxoid, Eastern and Western, Killed Virus.	American Home Products Corporation	112
5515.21	03-29-90	Equine Infectious Anemia Antibody Test Kit	Rhone Merieux, Inc	298
7410.00	03-15-90	Clostridium Chauvoei-Septicum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid.	Grand Laboratories Inc	303
9531.00	03-23-90	Allergenic Extract, Prescription Product	Nelco Laboratories Inc	359
A175.20	03-13-90	Bovine Rhinotracheitis ^{3}Virus Diarrhea-Parainfluenza Virus, Killed Virus, For Further Manufacture.	Grand Laboratories Inc	303
G160.00	03-26-90	Clostridium Chauvoei-Septicum-Haemolyticum-Novyi-Sordellii-Perfringens Types C & D Bacterin-Toxoid, For Further Manufacture.	Coopers Animal Health, Inc	107
H550.00	03-08-90	Pasteurella Multocida Toxoid, Killed Culture, For Further Manufacture	SmithKline Beckman Corporation	189

The regulations in 9 CFR part 102 also require that each person who prepares biological products that are subject to the Virus-Serum-Toxin Act (21 U.S.C. 151 *et seq.*) shall hold a U.S. Veterinary Biologics Establishment License. The regulations set forth the procedures for applying for a license, the criteria for determining whether a license shall be issued, and the form of the license. There were no U.S. Veterinary Biologics Establishment Licenses issued during the month of March 1990.

The regulations in 9 CFR parts 102 and 105 also contain provisions concerning the suspension, revocation, and termination of U.S. Veterinary Biological Product Licenses and U.S. Veterinary Biologics Establishment Licenses. There were no U.S. Veterinary Biologics Establishment Licenses or U.S. Veterinary Biological Product Licenses suspended, revoked or terminated during the month of March 1990.

Done in Washington, DC, this 13th day of June 1990.

James W. Glosser,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 90-14210 Filed 6-19-90; 8:45 am]

BILLING CODE 3410-34-M

DEPARTMENT OF COMMERCE

Foreign-Trade Zones Board

[Docket 15-90]

Proposed Foreign-Trade Zone—Pima County, AZ Tucson Customs Port of Entry Extension of Public Comment Period

The public comment period for the above case (55 FR 14847, 4/19/90), involving a proposed general-purpose foreign-trade zone in Pima County, adjacent to the Tucson Customs port of entry, is extended to August 2, 1990, to allow interested parties additional time in which to comment on the proposal.

Comments in writing are invited during this period. Submissions shall include 5 copies. Material submitted will be available at: Office of the Executive Secretary, Foreign-Trade Zones Board, U.S. Department of Commerce, room 2835, 14th and Pennsylvania Avenue, NW., Washington, DC 20230.

Dated: June 13, 1990.

John J. Da Ponte, Jr.,

Executive Secretary.

[FR Doc. 90-14181 Filed 6-19-90; 8:45 am]

BILLING CODE 3510-DS-M

International Trade Administration

[C-201-003]

Ceramic Tile From Mexico, Preliminary Results of Countervailing Duty Administrative Review

AGENCY: International Trade Administration/Import Administration Department of Commerce.

ACTION: Notice of preliminary results of countervailing duty administrative review.

SUMMARY: The Department of Commerce has conducted an administrative review of the

countervailing duty order on ceramic tile from Mexico. We preliminarily determine the total bounty or grant to be zero or *de. minimis* for 47 firms and 1.29 percent *ad valorem* for all other firms during the period January 1, 1987 through December 31, 1987. We invite interested parties to comment on these preliminary results.

EFFECTIVE DATE: June 20, 1990.

FOR FURTHER INFORMATION CONTACT: Laurie Goldman or Paul McGarr, Office of Countervailing Compliance, International Trade Administration, U.S. Department of Commerce, Washington, DC 20230; telephone: (202) 377-2786.

SUPPLEMENTARY INFORMATION:

Background

On May 9, 1989, the Department of Commerce (the Department) published in the Federal Register (54 FR 19930) the final results of its last administrative review of the countervailing duty order on ceramic tile from Mexico (47 FR 20013; May 10, 1982). On May 13 and May 31, 1988, a Mexican exporter, Azulejos Orion, S.A., and the Government of Mexico, respectively, requested an administrative review of the order. We initiated the administrative review on June 29, 1988 (53 FR 24470). The Department has now conducted this administrative review in accordance with section 751 of the Tariff Act of 1930 (the Tariff Act).

Scope of Review

Imports covered by this review are shipments of Mexican ceramic tile, including non-mosaic, glazed, and unglazed ceramic floor and wall tile. During the review period, such merchandise was classifiable under item numbers 532.2400 and 532.2700 of the *Tariff Schedules of the United States Annotated.* This merchandise is currently classifiable under item numbers 6907.10.0000, 6907.90.0000, 6908.10.0000 and 6908.90.0000 of the *Harmonized Tariff Schedule* (HTS). The HTS item numbers are provided for convenience and Customs purposes. The written description remains dispositive. The review covers the period January 1, 1987 through December 31, 1987 and 13 programs.

Analysis of Programs

(1) FOMEX

The Fund for the Promotion of Exports of Mexican Manufactured Products (FOMEX) is a trust of the Mexican Treasury Department, with the National Bank of Foreign Trade acting as trustee for the program. The National Bank of Foreign Trade, through financial institutions, makes FOMEX loans available at preferential rates to manufacturers and exporters for two purposes: Pre-export financing and export financing. We consider both pre-export and export FOMEX loans to be export bounties or grants since these loans are given only on merchandise destined for export.

We found that the annual interest rate financial institutions charged borrowers for peso-denominated FOMEX pre-export financing outstanding during the period of review ranged from 65.00 to 96.00 percent. The annual interest rate for dollar-denominated FOMEX export financing range from 5.50 to 7.50 percent during the period of review.

We consider the benefit from loans to occur when the interest is paid. Interest on FOMEX pre-export loans is paid at maturity, and those that matured during the period of review were obtained between November 1986 and November 1987. Since interest on FOMEX export loans is pre-paid, we calculated benefits from all FOMEX export loans received during the period of review.

The Banco de Mexico stopped publishing data on nominal and effective commercial lending rates after 1984. Therefore, as the basis for our benchmark, we have relied in part on the rates for the years 1981 through 1984, as published in the Banco de Mexico's *Indicadores Economicos y Moneda* (I.E.). We calculated the average difference between the Costo Porcentual Promedio (CPP) rates, the average cost of short-term funds to banks, and the I.E. effective rate for the period 1981 through 1984. We added this average difference to the 1986 and 1987 CPP rates. In this way, we calculated a benchmark of 135.27 percent for pre-export peso loans obtained in 1986, and 167.05 percent for pre-export peso loans obtained in 1987.

To determine the effective interest rate benchmark for dollar loans, we used an average of the quarterly weighted-average effective interest rates published in the *Federal Reserve Bulletin,* which was 9.81 percent in 1987.

Four of the 51 known exporters of this merchandise used this program during the period of review. Because we found that the exporters were able to tie their FOMEX loans to exports to specific countries, we measured the benefit only from FOMEX loans tied to U.S. shipments. We allocated each company's FOMEX benefit over the value of its total U.S. shipments during the period of review. We then weight-averaged the resulting benefits by each company's proportion of total exports to the United States, excluding exports from firms with significantly different aggregate benefits, in accordance with 19 CFR 355.20(d). We preliminarily determine the benefit from FOMEX pre-export loans during the review period to be 1.24 percent *ad valorem* and the benefit from FOMEX export loans to be 0.0001 percent *ad valorem* for all companies except those with zero or *de minimis* aggregate benefits.

(2) CEPROFI

Certificates of Fiscal Promotion (CEPROFI) are tax certificates used to promote the goals of the National Development Plan (NDP). They are granted in conjunction with investments in designated industrial activities or geographic regions and can be used to pay a wide range of federal tax liabilities. Article 26 of the decree revising the authority for issuing CEPROFI certificates, published in the *Diario Oficial* on January 22, 1986, requires each recipient to pay a four-percent supervision fee. The four-percent supervision fee is "paid in order to qualify for, or to receive" the CEPROFI certificates. Therefore, it is an allowable offset, as defined in section 771(6)(A) of the Tariff Act, from the gross bounty or grant.

During the review period, companies in Mexico could receive CEPROFI benefits under three provisions: Category I, which makes CEPROFI certificates available for the manufacture and processing of certain raw materials, construction and capital goods; Category II, which makes CEPROFI certificates available for particular industrial activities, and a third provision, which grants CEPROFI certificates to companies that purchase Mexican-made equipment.

The Department has determined that CEPROFI certificates granted for the purchase of Mexican-made equipment are not countervailable because such certificates are available to any company that purchases Mexican-made equipment. We consider the other two types of CEPROFI certificates to provide domestic bounties or grants because they are available only to certain industries.

For the two companies that receive CEPROFI benefits from the Category I or Category II provisions, we allocated each company's benefits, less the four-percent supervision fee, over the value of its sales to all markets during the period of review. We then weight-averaged the resulting benefits by each company's proportion of the total exports of the subject merchandise to the United States during the review period, excluding those companies with significantly different aggregate benefits. We preliminarily determine the benefit from this program during the

period of review to be 0.05 percent *ad valorem* for all companies except those with zero or *de minimis* aggregate benefits.

(3) Other Programs

We also examined the following programs and preliminarily determine that exporters of ceramic tile did not use them during the review period.

(A) Article 15 loans;
(B) State tax incentives;
(C) NDP preferential discounts;
(D) Bancomext loans;
(E) Delay of payments on loans;
(F) Delay of payments to PEMEX of fuel charges;
(G) Import duty reductions and exemptions;
(H) FONEI; and
(I) FOGAIN.

Firms Not Receiving Benefits

We preliminarily determine that the following 47 firms received zero or *de minimis* benefits during the period of review:

(1) Alfonso Cortez Coronel
(2) Augustin Cedillo Ruiz
(3) Aurelio Cedillo Ruiz
(4) Azulejos Decorativos Carillo
(5) Azulejos Orion
(6) Barros Procesados
(7) Barros y Pisos Artesanales
(8) Benjamin Chavez Torres
(9) Ceramica Santa Julia
(10) Eduardo S. Garcia de la Pena
(11) Ernesto Cortez
(12) Fernando Espinosa Sanchez
(13) Francisco Almanza Estrada
(14) Francisco Gallegos Garcia
(15) Francisco Rincon Leija
(16) Idelfonso Chavez Parga
(17) Ines Bustos
(18) Isabel Cortez
(19) Jesus Ambrosio Garcia R.
(20) Jesus Gallegos Olivares
(21) Jesus Garza Arocha
(22) Jesus Hernandez T.
(23) Jesus Jimenez Lucio
(24) Jose Angel Hernandez Martinez
(25) Jose Arellano Valdez
(26) Jose Davilla Torres
(27) Jose Dolores Hernandez Saucedo
(28) Jose Vasquez Garcia
(29) Juan Cortez Coronel
(30) Juan Rodriguez Rocha
(31) Julio Ulloa Rodriguez
(32) Ladrillera Monterrey
(33) Leopoldo Montiel Rincon
(34) Manual Alvarez Ramon
(35) Pablo Cortez Coronel
(36) Pedro Lopez Alonso
(37) Pisos Coloniales de Mexico, S.A.
(38) Ramon Jimenez De Leon
(39) Raul Leija
(40) Reynol Martinez Chapa
(41) Rosendo Rodriguez Hernandez
(42) Santos Rivera Tovar
(43) Sergio Garcia de las Fuentes
(44) Sotero Jalomo Reyna
(45) Teofilo Covarrubias Villareal
(46) Vicente Jalomo Reyna
(47) Zenon Cortez Coronel

Preliminary Results of Review

As a result of our review, we preliminarily determine the total bounty or grant during the period January 1, 1987 through December 31, 1987 to be zero or *de minimis* for 47 firms and 1.29 percent *ad valorem* for all other firms.

Therefore, the Department intends to instruct the Customs Service to liquidate, without regard to countervailing duties, shipments of this merchandise from the 47 firms listed above and to assess countervailing duties of 1.29 percent of the f.o.b. invoice price on shipments from all other firms exported on or after January 1, 1987 and on or before December 31, 1987.

The Department also intends to instruct the Customs Service to waive cash deposits of estimated countervailing duties, as provided by section 751(a)(1) of the Tariff Act, on shipments of this merchandise from the 47 firms listed above and to collect a cash deposit of estimated countervailing duties of 1.29 percent of the f.o.b. invoice price on shipments from all other firms entered, or withdrawn from warehouse, for consumption on or after the date of publication of the final results of this review.

Parties to the proceeding may request disclosure of the calculations methodology and interested parties may request a hearing not later than 10 days after the date of publication of this notice. Interested parties may submit written arguments in case briefs on these preliminary results within 30 days of the date of publication. Rebuttal briefs, limited to arguments raised in case briefs, may be submitted seven days after the time limit for filing the case brief. Any hearing, if requested, will be held seven days after the scheduled date for submission of rebuttal briefs. Copies of case briefs and rebuttal briefs must be served on interested parties in accordance with § 355.38(e) of the Commerce regulations. Any request for disclosure under an administrative protective order must be made no later than five days after the date of publication. The Department will publish the final results of this administrative review including the results of its analysis of issues raised in any case rebuttal brief or at a hearing.

This administrative review and notice are in accordance with section 751(a)(1) of the Tariff Act (19 U.S.C. 1675(a)(1)) and 19 CFR 355.22.

Dated: June 8, 1990.

Eric I. Garfinkel,

Assistant Secretary for Import Administration.

[FR Doc. 90-14182 Filed 6-19-90; 8:45 am]
BILLING CODE 3510-DS-M

National Oceanic and Atmospheric Administration

Public Hearings on the Draft Environmental Impact Statement and Draft Management Plan for the Proposed Chesapeake Bay National Estuarine Research Reserve in Virginia

AGENCY: Marine and Estuarine Management Division, Office of Ocean and Coastal Resource Management, National Ocean Service, National Oceanic and Atmospheric Administration, U.S. Department of Commerce.

ACTION: Public hearing notice.

SUMMARY: Notice is hereby given that the Marine and Estuarine Management Division, of the Office of Ocean and Coastal Resource Management (OCRM), National Ocean Service (NOS), National Oceanic and Atmospheric Administration (NOAA), U.S. Department of Commerce, will hold public hearings for the purpose of receiving comments on the Draft Environmental Impact Statement and Draft Management Plan (DEIS/DMP) prepared on the proposed designation of Goodwin Islands, Catlett Islands, Taskinas Creek, and Sweet Hall Marsh as the components of the Chesapeake Bay National Estuarine Research Reserve in Virginia

The Office of Ocean and Coastal Resource Management will hold public hearings at the following times and places:

Wednesday, July 11, 1990 at 7 p.m.—Watermen's Hall, Virginia Institute of Marine Science, College of William and Mary, Route 1208, Gloucester Point, VA.

Thursday, July 12, 1990 at 7 p.m.—van den Boogaard Center, 3510 King William Avenue and Route 30, West Point, VA.

The views of interested persons and organizations on the adequacy of the DEIS/DMP are solicited, and may be expressed orally and/or in written statements. Presentations will be scheduled on a first-come, first-heard basis, and may be limited to a maximum of five (5) minutes. The time allotment may be extended before the hearing when the number of speakers can be determined. All comments received at the hearing will be considered in the preparation of the Final Environmental Impact Statement (FEIS) and Final Management Plan.

The comment period for the DEIS/DMP will end on Monday, July 16, 1990. All written comments received by this deadline will be included in the FEIS.

FOR FURTHER INFORMATION CONTACT: Patmarie S. Maher, (202) 673-5122,

Marine and Estuarine Management Division, Office of Ocean and Coastal Resource Management, National Ocean Service, NOAA, 1825 Connecticut Avenue NW., suite 714, Washington, DC 20235. Copies of the draft environmental impact statement/draft management plan are available upon request to the Marine and Estuarine Management Division.

Federal Domestic Assistance Catalog Number 11.420 Coastal Zone Management Estuarine Sanctuaries.

Dated: May 18, 1990.

Virginia K. Tippie,

Assistant Administrator for Ocean Services and Coastal Zone Management.

[FR Doc. 90-14280 Filed 6-19-90; 8:45 am]

BILLING CODE 3510-08-M

Caribbean Fishery Management Council; Public Meeting

AGENCY: National Marine Fisheries Service, NOAA, Commerce.

The Caribbean Fishery Management Council will hold a public meeting of its Administrative Committee on June 26, 1990, at the Peace Talk Room, Travelodge Hotel, Isla Verde, Puerto Rico.

The Administrative Committee will begin its meeting at 9:30 a.m., to discuss issues related to the New England Fishery Management Council's proposal for the Atlantic Swordfish Fishery Management Plan. The Committee also will discuss tuna management under the Magnuson Fishery Conservation and Management Act, as well as discuss the Caribbean Council's administrative operations. The Committee will adjourn its meeting at 5 p.m.

For more information contact the Caribbean Fishery Management Council, Banco de Ponce Building, suite 1108, Hato Rey, Puerto Rico 00918-2577; telephone: (809) 766-5926.

Dated: June 15, 1990.

David S. Crestin,

Deputy Directory, Office of Fisheries Conservation and Management, National Marine Fisheries Services.

[FR Doc. 90-14281 Filed 6-19-90; 8:45 am]

BILLING CODE 3510-22-M

Marine Mammals; Issuance of Permit; Thomas R. Kieckhefer (P449)

On January 10, 1990, notice was published in the **Federal Register** (55 FR 891) that an application had been filed by Thomas R. Kieckhefer, Moss Landing Marine Laboratory, P.O. Box 450, Moss Landing, CA 95039-0450, to take by harassment humpback whales (*Megaptera novaeangliae*) for scientific purposes.

Notice is hereby given that on June 13, 1990, as authorized by the provisions of the Marine Mammal Protection Act of 1972 (16 U.S.C. 1361-1407) and the Endangered Species Act of 1973 (16 U.S.C. 1531-1543), the National Marine Fisheries Service issued a Permit for the above taking, subject to certain conditions set forth therein.

Issuance of this Permit, as required by the Endangered Species Act of 1973, is based on the finding that the Permit: (1) Was applied for in good faith; (2) will not operate to the disadvantage of the endangered species which is the subject of the Permit; and (3) is consistent with the purposes and policies set forth in section 2 of the Act. This permit was also issued in accordance with and is subject to parts 220-222 of title 50 CFR, the National Marine Fisheries Service regulations governing endangered species permits.

The Permit is available for review in the following offices:

Office of Protected Resources, National Marine Fisheries Service, 1335 East West Highway, Silver Spring, Maryland 20910;

Director, Southwest Region, National Marine Fisheries Service, 300 South Ferry Street, Terminal Island, California 90731.

Dated: June 13, 1990.

Nancy Foster,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 90-14188 Filed 6-19-90; 8:45 am]

BILLING CODE 3510-22-M

Marine Mammals; Permit Modification; Dr. Kenneth S. Norris, Dr. Randall S. Wells, Mr. Jan S. Ostman, and Dr. William T. Doyle (P20H); Modification No. 1 to Permit No. 603

Notice is hereby given that pursuant to the provisions of sections 216.33 (d) and (e) of the Regulations Governing the Taking and Importing of Marine Mammals (50 CFR part 216), Scientific Research Permit No. 603 issued to Dr. Kenneth S. Norris, Dr. Randall S. Wells, Mr. Jan S. Ostman, and Dr. William T. Doyle, Santa Cruz, California 95060 on August 17, 1987 (52 FR 31799), is modified as follows:

Section A.1 is replaced by:

1. Fifteen thousand (15,000) spinner dolphins (*Stenella longirostris*) may be incidentally harassed each year.

Section A.3 is added:

3. Four thousand (4,000) spotted dolphins (*Stenella attenuata*) may be incidentally harassed each year.

Section B. 1 and 4 are replaced by:

1. This research shall be conducted by the means, in the areas, and for the purposes set forth in the application as modified and the modification request.

4. The Permit Holder shall submit an annual report by December 31, each year the Permit is valid, indicating when, where, how many animals, by age and sex (as possible as well as species, have been taken in the course of authorized activities.

This modification becomes effective upon publication in the **Federal Register**.

Documents in connection with the above modification are available for review by appointment in the following offices:

Office of Protected Resources, National Marine Fisheries Service, 1335 East West Highway, Room 7324, Silver Spring, Maryland 20910 (301/427-2289);

Director, Southwest Region, National Marine Fisheries Service, NOAA, 300 South Ferry Street, Terminal Island, CA 90731-7451 (213/514-6196); and

Administrator, Pacific Area Office, National Marine Fisheries Service, NOAA, 2570 Dole Street, Room 106, Honolulu, HI 96822-2396 (808/955-8831).

Dated: June 13, 1990.

Nancy Foster,

Director, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 90-14189 Filed 6-19-90; 8:45 am]

BILLING CODE 3510-22-M

COMMISSION ON RAILROAD RETIREMENT REFORM

Meeting

SUMMARY: The Commission on Railroad Retirement Reform ("the Commission") will hold a public meeting on Tuesday, July 10, and continuing on Wednesday, July 11, 1990. The Commission was established by section 2101 of the Omnibus Budget Reconciliation Act of 1987, Public Law 100-203, enacted December 22, 1987.

DATE, TIME, AND PLACE: Tuesday, July 10, 9:30 a.m.-4 p.m. and reconvening on Wednesday, July 11, 1990, at 9 a.m.-4 p.m. The meeting will be held at the Association of American Railroads, 50 F Street, NW., Washington, DC (4th Floor Conference Center).

AGENDA: The open meetings will include the review of various staff memorandums, and discussion of final report items.

FOR ADDITIONAL INFORMATION: Contact Maureen Kiser, 202-254-3223, Commission on Railroad Retirement Reform, 1111 18th Street, NW., Washington, DC 20036.

SUPPLEMENTARY INFORMATION: See Federal Register, volume 54FR, NO. 4, Thursday, March 2, 1989, Page 8856.

Kenneth J. Zoll,

Executive Director.

[FR Doc. 90-14229 Filed 6-19-90; 8:45 am]

BILLING CODE 6820-63-M

COMMODITY FUTURES TRADING COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

AGENCY: Commodity Futures Trading Commission.

ACTION: Notice of information collection.

SUMMARY: The Commodity Futures Trading Commission has submitted information collection 3038-0005, Rules Relating to the Activities of Commodity Pool Operators and Commodity Trading Advisors to OMB for review and clearance under the Paperwork Reduction Act of 1980, Public Law 96-511. The information collected pursuant to this rule provides a basis for determining whether Commodity Pool Operators and Commodity Trading Advisors furnish customers meaningful information for use in making their determination to invest in commodities.

ADDRESS: Persons wishing to comment on this information collection should contact Gary Waxman, Office of Management and Budget, room 3228, NEOB, Washington, DC 20502, (202) 395-7340. Copies of the submission are available from Joe F. Mink, Agency Clearance Officer, (202) 254-9735.

Title: Rules Relating to the Activities of Commodity Pool Operators and Commodity Trading Advisors.

Control Number: 3038-0005.

Action: Extension.

Respondents: Commodity Pool Operators and Commodity Trading Advisors.

Estimated Annual Burden: 69,461.50.

Respondents and regulation (17 CFR)	Estimated No. of respondents	Annual responses	Est. avg. hours per response
Commodity pool operators and commodity trading advisors:			
Reporting:			
4.12(b)	25.00	1.00	0.50
4.14(a)(8)	100.00	1.00	0.50
4.5	300.00	1.00	1.00
4.6	50.00	2.00	1.00
4.13(b)(1)	125.00	1.00	1.00
4.13(b)(2)	325.00	12.00	0.10
4.21	375.00	1.00	4.00
4.22(a)	510.00	1.00	10.00
4.22(c)	450.00	6.00	4.50
4.31	700.00	2.00	2.00
1.33(d)	100.00	12.00	6.00
Recordkeeping:			
4.13(b)(2)(ii)	450.00	1.00	13.00
4.23	502.00	1.00	52.00
4.32	150.00	1.00	52.00

Issued in Washington, DC, on June 14, 1990.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 90-14242 Filed 6-19-90; 8:45 am]

BILLING CODE 6351-01-M

Agricultural Advisory Committee Meeting

This is to give notice, pursuant to section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, section 10(a) and 41 CFR 101-6.1015(b), that the Commodity Futures Trading Commission's Agricultural Advisory Committee will conduct a public meeting in the Fifth Floor Hearing Room at the Commission's Washington, DC headquarters located at room 532, 2033 K Street, NW., Washington, DC 20581, on July 13, 1990, beginning at 9 a.m. and lasting until 3:30 p.m. The agenda will consist of:

Agenda

1. Discussion of various delivery issues, including proposed amendments to Chicago Board of Trade grain futures contracts;

2. Status report on reauthorization/jurisdiction;

3. Discussion of ongoing regulatory and self-regulatory intiatives;

4. Update on electronic trading;

5. Off-exchange issues, including commercial forward contracts and swaps;

6. Discussion of international issues affecting agriculture; and

7. Other issues for Committee consideration; timing of next meeting; other Committee business.

The purpose of this meeting is to solicit the views of the Committee on the above-listed agenda matters. The Advisory Committee was created by the Commodity Futures Trading Commission for the purpose of receiving advice and recommendations on agricultural issues. The purposes and objectives of the Advisory Committee are more fully set forth in the May 9, 1989 third renewal charter of the Advisory Committee.

The meeting is open to the public. The Chairman of the Advisory Committee, Commissioner Kalo A. Hineman, is empowered to conduct the meeting in a fashion that will, in his judgment, faciliate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Advisory Committee should mail a copy of the statement to the attention of: The Commodity Futures Trading Commission Agricultural Advisory Committee c/o Charles O. Conrad, Commodity Futures Trading Commission, 2033 K Street, NW., Washington, DC 20581, before the meeting. Members of the public who wish to make oral statements should also inform Mr. Conrad in writing at the foregoing address at least three business days before the meeting. Reasonable provision will be made, if time permits, for an oral presentation of no more than five minutes each in duration.

Issued by the Commission in Washington, DC on June 14, 1990.

Jean A. Webb,

Secretary of the Commission.

[FR Doc 90-14184 Filed 6-19-90; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF ENERGY

Systematic Evaluation Program at Department of Energy's Rocky Flats Plant, CO; Response to Recommendation 90-5 of the Defense Nuclear Facilities Safety Board

AGENCY: Department of Energy.

ACTION: Notice and request for public comment.

SUMMARY: Pursuant to section 315(d) of the Atomic Energy Act of 1954, as amended, 42 U.S.C. 2286(d) the Department of Energy (DOE) hereby publishes notice of the response of the Secretary of Energy (Secretary) to Recommendation 90-5 of the Defense Nuclear Facilities Safety Board, 55 FR 21429-21430 (May 24, 1990), concerning a Systematic Evaluation Program at the Department of Energy's Rocky Flats Plant, Colorado. DOE hereby requests public comment on the response of the Secretary to Recommendation 90-5.

DATES: Comments, data, views, or arguments concerning the Secretary's response are due on or before July 20, 1990.

ADDRESSES: Send comments, data, views, or arguments concerning the Secretary's response to: Defense Nuclear Facilities Safety Board, 600 E Street NW., suite 675, Washington, DC 20004.

FOR FURTHER INFORMATION CONTACT: Steven Blush, Director, Office of Nuclear Safety, Department of Energy, 1000 Independence Avenue SW., Washington, DC 20585.

Dated: June 12, 1990.

Joseph E. Fitzgerald,

Acting Director, Office of Nuclear Safety.

June 13, 1990.

Honorable John T. Conway,

Chairman, Defense Nuclear Facilities Safety Board, 600 E Street NW., suite 675, Washington, DC 20004.

Dear Chairman Conway: I have received your May 18, 1990 letter enclosing the Defense Nuclear Facilities Safety Board's recommendations regarding plutonium processing operations at Rocky Flats Plant.

I agree with the Board's recommendations and have asked Defense Programs to prepare a detailed implementation plan to systematically assess the equipment and structural improvements necessary for assuring safety at Rocky Flats.

This constitutes a final decision by the Department on the Board's Recommendation 90-5. As required by section 315 of Public Law 100-456, we will submit both to the Board and to the Congress a plan to implement these recommendations within 90 days of publication of this letter in the **Federal Register.**

Sincerely,

James D. Watkins,

Admiral, U.S. Navy (Retired).

[FR Doc. 90-14264 Filed 6-19-90; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket Nos. ER90-416-000, et al.]

Alabama Power Co., et al., Electric Rate, Small Power Production, and Interlocking Directorate Filings

June 13, 1990.

Take notice that the following filings have been made with the Commission:

1. Alabama Power Co.

[Docket No. ER90-416-000]

Take notice that on June 1, 1990, Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (Southern electric system) tendered for filing a change in the fuel pricing methodology for use in dispatching generating units on the Southern electric system by proposing to adopt "marginal replacement fuel cost."

In its filing Alabama discusses the effect of marginal replacement fuel cost dispatch on Alabama Power Company's Rate Schedule REA-1 and Rate Schedule MUN-1 between Alabama Power Company and Alabama Municipal Electric Authority.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

2. Southern Company Services, Inc.

[Docket No. ER90-423-000]

Take notice that on June 1, 1990, Southern Company Services, Inc., acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company, and Savannah Electric and Power Company (Southern Companies) tendered for filing a change in practice under Service Schedule A and Service Schedule C of the interchange Contract between Florida Power Corporation and Southern Companies are proposing to adopt marginal replacement fuel cost for use in generating unit dispatch. Marginal replacement fuel cost dispatch will only be implemented after it is accepted without refund obligation under all wholesale and retail rates of Southern Companies. Southern Companies request that the change in practice be allowed to become effective on August 1, 1990.

Commente date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

3. Mississippi Power Co.

[Docket No. ER90-435-000]

Take notice that on June 1, 1990, Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (Southern electric system) tendered for filing a change in the fuel pricing methodology for use in dispatching generating units on the Southern electric system by proposing to adopt "marginal replacement fuel cost."

In its filing Mississippi Power Company discusses the effect of marginal replacement fuel cost dispatch on Mississippi Power Company's Service Schedule MR-16D.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

4. Gulf Power Co.

[Docket No. ER90-408-000]

Take notice that on June 1, 1990, Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (Southern electric system) tendered for filing a change in the fuel pricing methodology for use in dispatching generating units on the Southern electric system by proposing to adopt "marginal replacement fuel cost."

In its filing Gulf Power discusses the effect of marginal replacement fuel cost dispatch on Gulf Power Company's service to Florida Public Utilities under FERC Electric Tariff Second Revised Volume No. 1.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

5. Gulf Power Co.

[Docket No. ER90-4098-000]

Take notice that on June 1, 1990, Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (Southern electric system) tendered for filing changes in the fuel pricing methodology for use in dispatching generating units on the Southern electric

system by proposing to adopt "marginal replacement fuel cost."

In its filing Gulf Power discusses the effect of marginal replacement fuel cost dispatch on the Interconnection Agreement and Agreement for Transmission Service between Bay Resource Management, Inc. and Gulf Power Company.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

6. Central Vermont Public Service Corp.

[Docket No. ER90-412-000]

Take notice that on June 1, 1990, Central Vermont Public Service Corporation (Central Vermont) tendered for filing its 1989 Cost Report required under Article 2.3(A) on Original Sheet No. 21 of FERC Electric Tariff, Original Volume No. 4 of Central Vermont under which Central Vermont provides Unreserved System Power Service to the following Customers:

Lyndonville Electric Department
Village of Ludlow Electric Light Department
Village of Johnson Water and Light Department
Village of Hyde Park Water and Light Department

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

7. Gulf Power Co.

[Docket No. ER90-402-000]

Take notice that on June 1, 1990, Alabama Power Company, Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (Southern electric system) tendered for filing a change in the fuel pricing methodology for use in dispatching generating units on the Southern Companies system by proposing to adopt "marginal replacement fuel cost."

In its filing Gulf Power Company discusses the effect of marginal replacement fuel cost dispatch on Gulf Power Company's service to Blountstown under FERC Electric Tariff Second Revised Volume No. 1.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

Central Vermont Public Service Corp.

[Docket No. ER90-413-000]

Take notice that on June 1, 1990, Central Vermont Public Service Corporation (Central Vermont) tendered for filing its 1989 Cost Report required under Article 2.4 on Second Revised Sheet No. 18 of FERC Electric Tariff, Original Volume No. 3, of Central Vermont under which Central provides the transmission and distribution service to the following Customers:

Vermont Electric Cooperative, Inc.
Lyndonville Electric Department
Village of Ludlow Electric Light Department
Village of Johnson Water and Light Department
Village of Hyde Park Water and Light Department
Allied Power and Light Company
Rochester Electric Light and Power Company

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 90-14191 Filed 6-19-90; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. ER90-440-000, et al.]

Georgia Power Co., et al., Electric Rate, Small Power Production, and Interlocking Directorate Filings

June 12, 1990.

Take notice that the following filings have been made with the Commission:

1. Georgia Power Co.

[Docket No. ER90-440-000]

Take notice that on June 1, 1990, Georgia Power Company (Georgia Power) tendered for filing a letter advising the Commission of the proposed change by the operating companies of the Southern electric system from "blended replacement fuel cost" to "marginal replacement fuel cost" for purpose of dispatching the generating units on the Southern electric system.

Georgia Power states that while the change in dispatch methodology may reduce energy costs under its Full Requirements and Partial Requirements wholesale tariffs, the tariffs themselves will not be changed. Georgia Power further states its belief that the proposed change in dispatch methodology does not constitute a change in the Full Requirements and Partial Requirements wholesale tariffs requiring a rate change filing under the Federal Power Act.

Georgia Power states that it has served a copy of its filing on all of its jurisdictional customers.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

2. Southern Company Services, Inc.

[Docket Nos. ER90-427-000]

Take notice that on June 1, 1990, Southern Company Services, Inc., acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, and Mississippi Power Company (Southern Companies), tendered for filing a change in practice under Service Schedule A, Service Schedule B, and Service Schedule C of the Interchange Contract between Duke Power Company Southern Companies dated June 1, 1961, as amended. Southern Companies are proposing to adopt marginal replacement fuel cost for use in generating unit dispatch. Marginal replacement fuel cost dispatch will only be implemented after it is accepted without refund obligation under all wholesale and retail rates of Southern Companies. Southern Companies request that the change in practice be allowed to become effective on August 1, 1990.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

3. Alabama Power Co.

[Docket No. ER90-414-000]

Take notice that on June 1, 1990, Alabama Power Company tendered for filing a change in practice under the contract executed by the United States of America, Department of Energy acting by and through the Southeastern Power Administration and Alabama Power Company dated January 29, 1985. Alabama Power Company, along with Georgia Power Company, Gulf Power Company, Mississippi Power Company and Savannah Electric and Power Company (Southern Companies), is proposing to adopt marginal replacement fuel cost for use in generating unit dispatch. Marginal replacement fuel cost dispatch will only be implemented after it is accepted without refund obligation under all wholesale and retail rates of Southern Companies. Alabama Power Company requests that the change in practice be

allowed to become effective on August 1, 1990.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

4. Southern Company Services, Inc.

[Docket Nos. ER90-428-000]

Take notice that on June 1, 1990, Southern Company Services, Inc., acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, and Mississippi Power Company, and Savannah Electric and Power Company (Southern Companies), tendered for filing a change in practice under Service Schedules A, B, and C of the Interchange Contract between Florida Power & Light Company and Southern Companies dated October 18, 1979, as amended. Southern Companies are proposing to adopt marginal replacement fuel cost for use in generating unit dispatch. Marginal replacement fuel cost dispatch will only be implemented after it is accepted without refund obligation under all wholesale and retail rates of Southern Companies. Southern Companies request that the change in practice be allowed to become effective on August 1, 1990.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

5. San Diego Gas & Electric Co.

[Docket No. ER90-439-000]

Take notice that on June 4, 1990, San Diego Gas & Electric Company (SDG&E) tendered for filing a change of rates for transmission service as embodied in the following SDG&E Agreement with Southern California Edison Company (Edison), which reflects a decrease in the rate of return from 10.90 percent to 10.86 percent authorized by the California Public Utilities Commission (CPUC) to be made effective January 1, 1990, and other updated costs for transmission network facilities.

1. Short Term Firm Transmission Service Agreement, Rate Schedule FERC 58;

2. Interruptible Transmission Service Agreement, Rate Schedule FERC 59; and

3. Firm Transmission Service Agreement, Rate Schedule FERC 60.

SDG&E requests waiver of the Commission's notice requirements and an effective date of January 1, 1990.

Copies of the filing were served upon the Public Utilities Commission of the State of California and Edison.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

6. Southern Company Services, Inc.

[Docket No. ER90-426-000]

Take notice that on June 1, 1990, Southern Company Services, Inc. acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, and Mississippi Power Company (Southern Companies), tendered for filing a change in practice under Service Schedule A, Service Schedule B, and Service Schedule C of the Interchange Contract between Tennessee Valley Authority and Southern Companies dated July 1, 1965, as amended. Southern Companies are proposing to adopt marginal replacement fuel cost for use in generating unit dispatch. Marginal replacement fuel cost dispatch will only be implemented after it is accepted without refund obligation under all wholesale and retail rates of Southern Companies. Southern Companies request that the change in practice be allowed to become effective on August 1, 1990.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

7. Southern Company Services, Inc.

[Docket No. ER90-425-000]

Take notice that on June 1, 1990, Southern Company Services, Inc., acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, and Mississippi Power Company (Southern Companies), tendered for filing a change in practice under the Interchange Contract between South Carolina Electric & Gas Company and Southern Companies dated November 1, 1963, as amended. Southern Companies are proposing to adopt marginal replacement fuel cost for use in generating unit dispatch. Marginal replacement fuel cost dispatch will only be implemented after it is accepted without refund obligation under all wholesale and retail rates of Southern Companies. Southern Companies request that the change in practice be allowed to become effective on August 1, 1990.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

8. Southern Company Services, Inc.

[Docket No. ER90-417-000]

Take notice that on June 1, 1990, Southern Company Services, Inc., acting on behalf of Alabama Power Company, Georgia Power Company, Gulf Power Company, and Mississippi Power Company (Southern Companies), tendered for filing a letter agreement amending a practice in Service Schedule E to the Interchange Contract dated December 15, 1980, as amended, between the City of Tallahassee and Southern Companies. The Southern electric system is promosing to adopt marginal replacement fuel cost for use in generating unit dispatch. Marginal replacement fuel dispatch will only be implemented after it is accepted without refund obligation under all wholesale and retail rates of Southern Companies. Southern Companies request that the amendment be allowed a become effective on August 1, 1990.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

9. Niagara Mohawk Power Corp.

[Docket Nos. ER88-304-004, ER88-305-005, and ER89-31-001]

Take notice that on June 6, 1990, Pursuant to the Commission's letter order dated May 23, 1990, Niagara Mohawk Power Corporation tendered for filing its Compliance Refund Report. Niagara Mohawk states that on May 24, 1990, it tendered a total of $21,124,074.67 (principal and interest) to New York State Electric & Gas Corporation and $709,518.73 to Central Hudson Gas & Electric Corporation.

Niagara Mohawk states that copies of its Report were served on the New York Public Service Commission and the affected wholesale customers.

Comment date: June 27, 1990, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capital Street, NE. Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 90-14192 Filed 6-19-90; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP90-1487-000, et al.]

ANR Pipeline Co., et al.; Natural Gas Certification Filings

June 21, 1990.

Take notice that the following filings have been made with the Commission:

1. ANR Pipeline Co.

[Docket No. CP90-1487-000]

Take notice that on June 4, 1990, ANR Pipeline Company (ANR),[1] 500 Renaissance Center, Detroit, Michigan 48243, filed an application with the Commission in Docket No. CP90-1487-000 pursuant to section 7(b) of the Natural Gas Act (NGA), for permission and approval to abandon a firm transportation service it performed for Texas Gas Transmission Corporation (Texas Gas), all as more fully set forth in the application which is open to public inspection.

ANR states that the Commission order issued February 20, 1970, in Docket No. CP69-249 (43 FPC 212), which amended the June 24, 1969, order issued in Docket No. CP69-249 (43 FPC 828), authorized ANR to provide a firm transportation service of 3,000 Mcf of natural gas per day from a St. Mary Parish, Louisiana, receipt point to an interconnection of ANR's and Texas Gas' pipeline facilities near Eunice, Acadia Parish, Louisiana, for Texas Gas' account. ANR, with Texas Gas' consent, now proposes to abandon its firm transportation service pursuant to its FERC Rate Schedule X-15, effective February 23, 1990.

Comment date: July 3, 1990, in accordance with Standard Paragraph F at the end of the notice.

Equitable Resources Energy Co. (Successor-in-Interest to Equitable Resources Exploration, Inc. and Eastern Kentucky Production Co.

[Docket Nos. CI86-245-003, *et al.*, and CI90-31-000]

Take notice that on December 15, 1989, Equitable Resources Energy Company (Equitable Energy) of Suite 2900, 330 Grant Street, Pittsburgh, Pennsylvania 15219, filed an application pursuant to section 7 of the Natural Gas Act and parts 154 and 157 of the Federal Energy Regulatory Commission's (Commission) regulations thereunder as successor-in-interest to Equitable Resources Exploration, Inc. (Equitable Exploration) and to Eastern Kentucky Production Company (Eastern Kentucky) to amend the certificates of public convenience and necessity previously held by Equitable Exploration and Eastern Kentucky to reflect Equitable Energy as the certificate holder and to redesignate the related rate schudules, all as more fully set forth in the application which is on file with the Commission and open for public inspection.

Effective January 1, 1989, Equitable Exploration and Eastern Kentucky merged into Equitable Energy with Equitable Energy continuing as the surviving corporation. Prior to the merger Equitable Exploration and Eastern Kentucky made sales under the certificates and rate schedules listed in Appendix A. In addition, Equitable exploration also made sales under small producer authorization issued in FPC Order No. 411 and under the contracts listed in Appendix B. Equitable Energy requests that the certificates and rate schedules listed in Appendix A be redesignated in the name of Equitable Energy and that the contracts listed in Appendix B be accepted as rate schedules.

Comment date: July 2, 1990, in accordance with the subparagraph first of Standard Paragraph F at the end of the notice.

Appendix A

Equitable Resources Exploration, Inc. FERC Gas Rate Schedule No.	Certificate Docket No.	Purchaser
1	CI86-245	East Tennessee Natural Gas Company.

Eastern Kentucky Production Company FERC Gas Rate Schedule No.	Certificate Docket No.	Purchaser
12	CI84-498	Kentucky West Virginia Gas Company
2	CI88-651	Equitrans, Inc.
3	CI88-651	Equitrans, Inc.
4	CI88-651	Equitrans, Inc.
4	CI88-651	Equitrans, Inc.
5	CI88-651	Equitrans, Inc.
6	CI88-651	Equitrans, Inc.
7	CI88-651	Equitrans, Inc.
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17	CI88-651	Equitrans, Inc.
18	CI88-651	Equitrans, Inc.
19	CI88-651	Equitrans, Inc.
20	CI88-651	Equitrans, Inc.

Appendix B

DOCKET NO. CI90-31-000 PROPOSED RATE SCHEDULES FOR SALES MADE BY EQUITABLE RESOURCES EXPLORATION, INC. UNDER SMALL PRODUCER AUTHORIZATION

Contract date	Contract No.	Purchaser
4-10-56	A-191-WV	Columbia Gas Transmission Corp.
7-15-56	A-192-WV	Columbia Gas Transmission Corp.
8-7-56	A-195-WV	Columbia Gas Transmission Corp.
3-18-57	A-197-WV	Columbia Gas Transmission Corp.
2-19-57	A-198-WV	Columbia Gas Transmission Corp.
6-2-58	A-207-WV	Columbia Gas Transmission Corp.
9-1-59	A-219-WV	Columbia Gas Transmission Corp.
6-1-6	A-223-WV	Columbia Gas Transmission Corp.
11-15-60	A-238-WV	Columbia Gas Transmission Corp.
6-1-61	A-248-WV	Columbia Gas Transmission Corp.
6-1-61	A-254-WV	Columbia Gas Transmission Corp.
4-7-62	A-256-WV	Columbia Gas Transmission Corp.
10-12-62	A-266-WV	Columbia Gas Transmission Corp.
10-22-62	A-267-WV	Columbia Gas Transmission Corp.
10-22-62	A-268-WV	Columbia Gas Transmission Corp.
1-31-63	A-273-WV	Columbia Gas Transmission Corp.
8-27-63	A-282-WV	Columbia Gas Transmission Corp.
9-24-63	A-283-WV	Columbia Gas Transmission Corp.
10-17-63	A-285-WV	Columbia Gas Transmission Corp.
2-7-64	A-292-WV	Columbia Gas Transmission Corp.
3-19-64	A-293-WV	Columbia Gas Transmission Corp.
11-2-64	A-308-WV	Columbia Gas Transmission Corp.
3-3-65	A-314-WV	Columbia Gas Transmission Corp.

[1] Previously known as Michigan Wisconsin Pipe Line Company.

DOCKET NO. CI90-31-000 PROPOSED RATE SCHEDULES FOR SALES MADE BY EQUITABLE RESOURCES EXPLORATION, INC. UNDER SMALL PRODUCER AUTHORIZATION—Continued

Contract date	Contract No.	Purchaser
5-6-65	A-317-WV	Columbia Gas Transmission Corp.
3-17-66	A-331-WV	Columbia Gas Transmission Corp.
10-19-66	A-349-WV	Columbia Gas Transmission Corp.
4-11-67	A-363-WV	Columbia Gas Transmission Corp.
10-24-67	A-374-WV	Columbia Gas Transmission Corp.
11-6-67	A-375-WV	Columbia Gas Transmission Corp.
2-19-68	A-378-WV	Columbia Gas Transmission Corp.
8-27-68	A-383-WV	Columbia Gas Transmission Corp.
9-10-68	A-386-WV	Columbia Gas Transmission Corp.
9-20-68	A-387-WV	Columbia Gas Transmission Corp.
11-5-68	A-389-WV	Columbia Gas Transmission Corp.
11-5-68	A-391-WV	Columbia Gas Transmission Corp.
11-21-68	A-392-WV	Columbia Gas Transmission Corp.
11-27-68	A-393-WV	Columbia Gas Transmission Corp.
1-13-69	A-395-WV	Columbia Gas Transmission Corp.
6-4-69	A-400-WV	Columbia Gas Transmission Corp.
8-29-69	A-403-WV	Columbia Gas Transmission Corp.
10-22-69	A-407-WV	Columbia Gas Transmission Corp.
1-7-70	A-409-WV	Columbia Gas Transmission Corp.
7-13-70	A-413-WV	Columbia Gas Transmission Corp.
2-3-71	A-425-WV	Columbia Gas Transmission Corp.

DOCKET NO. CI90-31-000 PROPOSED RATE SCHEDULES FOR SALES MADE BY EQUITABLE RESOURCES EXPLORATION, INC. UNDER SMALL PRODUCER AUTHORIZATION—Continued

Contract date	Contract No.	Purchaser
5-5-71	A-426-WV	Columbia Gas Transmission Corp.
9-10-71	A-428-WV	Columbia Gas Transmission Corp.
2-9-72	A-431-WV	Columbia Gas Transmission Corp.
2-9-72	A-432-WV	Columbia Gas Transmission Corp.
6-14-72	A-433-WV	Columbia Gas Transmission Corp.
11-3-72	A-435-WV	Columbia Gas Transmission Corp.
11-8-72	A-436-WV	Columbia Gas Transmission Corp.
11-21-72	A-437-WV	Columbia Gas Transmission Corp.
3-12-73	A-442-WV	Columbia Gas Transmission Corp.
5-25-73	A-443-WV	Columbia Gas Transmission Corp.
5-25-73	A-444-WV	Columbia Gas Transmission Corp.
5-2-75	AP-20775-WV	Columbia Gas Transmission Corp.
5-2-75	AP-20776-PA	Columbia Gas Transmission Corp.
5-12-75	AP-20789-WV	Columbia Gas Transmission Corp.
5-14-75	AP-20800-WV	Columbia Gas Transmission Corp.
9-16-75	AP-20946-WV	Columbia Gas Transmission Corp.
12-13-76	AP-21528-WV	Columbia Gas Transmission Corp.
10-10-77	AP-22077-WV	Columbia Gas Transmission Corp.
9-26-78	AP-22945-WV	Columbia Gas Transmission Corp.
3-5-64	2882	CNG Transmission Corp.
12-26-68	3383	CNG Transmission Corp.
2-24-69	3393	CNG Transmission Corp.
2-12-70	3484	CNG Transmission Corp.

DOCKET NO. CI90-31-000 PROPOSED RATE SCHEDULES FOR SALES MADE BY EQUITABLE RESOURCES EXPLORATION, INC. UNDER SMALL PRODUCER AUTHORIZATION—Continued

Contract date	Contract No.	Purchaser
2-16-71	3552	CNG Transmission Corp.
9-22-76	3851	CNG Transmission Corp.
1-6-77	3853	CNG Transmission Corp.
11-2-60	A-229-WV	Columbia Gas Transmission Corp.
3-30-61	A-236-WV	Columbia Gas Transmission Corp.
7-8-66	A-342-WV	Columbia Gas Transmission Corp.
11-27-67	A-376-WV	Columbia Gas Transmission Corp.

3. Panhandle Eastern Pipe Line Co.

Docket No. CP90-1479-000, Docket No. CP90-1482-000, Docket No. CP90-1484-000, Docket No. CP90-1485-000

Take notice that on June 4, 1990, Panhandle Eastern Pipe Line Company (Panhandle), Post Office Box 1642, Houston, Texas 77251, filed in the respective dockets prior notice requests pursuant to sections 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of various shippers under its blanket certificate issued in Docket No. CP86-585-000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the prior notice requests which are on file with the Commission and open to public inspection.[2]

A summary of each transportation service which includes the shippers identity, the peak day, average day and annual volumes, the receipt point(s), the delivery point(s), the applicable rate schedule, and the docket number and service commencment date of the 120-day automatic authorization under section 284.223 of the Commission's Regulations is provided in the attached appendix.

Comment date: July 27, 1990, in accordance with Standard Paragraph G at the end of this notice.

[2] These prior notice requests are not consolidated.

Appendix

Docket No. (date filed)	Applicant	Shipper name contract No.	Peak day [1] average annual	Points of		Start up date rate schedule	Related dockets [2]
				Receipt	Delivery		
CP90-1479-000 (6-4-90)	Panhandle Eastern Pipe Line Co.	Kerr Mcgee Corp.	5,000 5,000 1,625,000	CO, KS OK, TX	KS	4-1-90 PT	CP86-585-000, ST90-2672-000
CP90-1482-000 (6-4-90)	Panhandle Eastern Pipe Line Co.	Northern Indiana Fuel & Light Co.	5,612 5,612 2,048,380	KS	IN	4-1-90 PT	CP86-585-000, ST90-2672-000
CP90-1484-000 (6-4-90)	Panhandle Eastern Pipe Line Co.	Continental Energy	200 200 73,300	CO, IL KS, MI OK, TX	KS	4-1-90 PT	CP86-585-000, ST90-2672-000
CP90-1485-000 (6-4-90)	Panhandle Eastern Pipe Line Co.	Sunnybrook Tansmission Inc.	3,000 3,000 1,095,000	KS, IL	IL	4-1-90 PT	CP86-585-000, ST90-2672-000

[1] Quantities are shown in Dt. unless otherwise indicated.
[2] The CP docket corresponds to applicants blanket transportation certifiate. If an ST docket is shown, 120-day transportation service was reported in it.

4. United Gas Pipe Line Co., Sea Robin Pipeline Co.

[Docket No. CP90-1505-000, Docket No. CP90-1506-000]

Take notice that on June 7, 1990, United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77251-1478, and Sea Robin Pipeline Company (Sea Robin), P.O. Box 1478, Houston, Texas, 77251-1478, filed in the respective dockets prior notice requests pursuant to sections 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of two shippers under United's blanket certificate issued in Docket No. CP88-6-000 and Sea Robin's blanket certificate issued in Docket No. CP88-824-000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the prior notice requests which are on file with the Commission and open to public inspection.[3]

Information applicable to each transaction, including the identity of the shipper, the peak day, average day and annual volumes, and the initiation service dates and related docket numbers of the 120-day transactions under section 284.223 of the Commission's Regulations, has been provided by United and Sea Robin and is summarized in the attached appendix.

United and Sea Robin state that each of the proposed services would be provided under an executed transportation agreement, and that United and Sea Robin would charge the rates and abide by the terms and conditions of the appropriate transportation rate schedule. It is asserted that both transportation services would be carried out on an interruptible basis. It is further asserted that existing facilities would be used for the transportation services and no construction of additional facilities would be required. It is explained that the gas would be received by United and Sea Robin at designated points on their systems and would be delivered for the shippers' accounts at designated points of interconnection.

Comment date: July 27, 1990, in accordance with Standard Paragraph G at the end of this notice.

[3] These prior notice requests are not consolidated.

Appendix

Docket No.	Shipper name	Peak day [1] average annual	Start-up date	Related [2] dockets
CP90-1505-000	Shell Gas Trading Co.	206,000 206,000 75,190,000	4/1/90	ST90-995
CP90-1506-000	Oxy U.S.A.	5,150 5,150 1,879,750	5/1/90	ST90-3070

[1] Quantities are shown in MMBtu equivalent.
[2] United and Sea Robin reported their 120-day transportation service in the referenced ST dockets.

5. Transcontinental Gas Pipe Line Corp.

[Docket No. CP89-7-005]

Take notice that on May 29, 1990, Transcontinental Gas Pipe Line Corporation (Transco), P.O. Box 1396, Houston, Texas 77251, filed pursuant to section 7(c) of the Natural Gas Act to amend the certificate authorization issued by the Commission on July 27, 1989, in Docket No. CP89-7-000, *et al.*, 48 FERC ¶ 61,121. The Commission's Order authorized Transco to provide a new firm storage service to eight customers including Continental Energy Associates (Continental) under a new Rate Schedule SS-2 for a term of fifteen years. Transco states that the purpose of the amendment is to obtain authorization to reallocate among the majority of existing Rate Schedule SS-2 customers 1,650 MMcf of storage capacity and 15,000 Mcf per day of withdrawal capacity which was initially dedicated to Continental.

On July 20, 1989, Continental notified Transco of its decision to withdraw from the SS-2 project and to terminate its precedent agreement because of Continental's inability to obtain approval from its bank to undertake the financial commitment of demand charges associated with the service.

Subsequent to Continental's withdrawal, Transco states that it offered the capacity previously dedicated to Continental to all SS–2 customers. As a result of such discussions, Transco seeks Commission authorization to reallocate the 15,000 Mcf per day of storage deliverability and the 1,650 MMcf of capacity among the SS–2 storage customers as follows:

SS–2 customer	Certificated level		Revised level	
	Withdrawal capacity Mcf/d	Storage capacity MMcf	Withdrawal capacity Mcf/d	Storage capacity MMcf
Consolidated Edison Company of New York Inc.	15,000	1,650	18,700	2,057
Continental Energy Associates Limited Partnership	15,000	1,650	0	0
Energy Marketing Exchange, Inc.	3,000	330	3,300	363
Long Island Lighting Company	20,000	2,200	22,400	2,464
New Jersey Natural Gas Company	6,800	748	8,100	891
Pennsylvania Gas and Water Company	25,000	2,750	25,000	2,750
South Jersey Gas Company	13,200	1,452	15,500	1,705
UGI Corporation	2,000	220	7,000	770
Total	100,000	11,000	100,000	11,000

Transco states that the proposed reallocation of capacity would have no effect upon the certificated facilities or rates associated with the SS–2 service.

Comment date: July 3, 1990, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

6. United Gas Pipe Line Co.

[Docket Nos. CP90–1457–000,[4] CP90–1458–000, CP90–1459–000, CP90–1460–000, CP90–1461–000]

Take notice that on May 31, 1990, United Gas Pipe Line Company (United), P.O. Box 1478, Houston, Texas 77251–1478, filed in the above referenced dockets, as supplemented June 8, 1990, in Docket No. CP90–1460–000 prior notice requests pursuant to section 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of various shippers under the authorization issued in Docket No. CP88–6–000 issued pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the prior notice requests which are on file with the Commission and open to public inspection and in the attached appendix.

Information applicable to each transaction including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the docket numbers and initiation dates of the 120-day transactions under section 284.223 of the Commission's Regulations has been provided by the United and is included in the attached appendix.

United also states that it would provide the service for each shipper under an executed transportation agreement, and that the United would charge rates and abide by the terms and conditions of the referenced transportation rate schedule(s).

Comment date: July 2, 1990, in accordance with Standard Paragraph F at the end of this notice.

[4] These prior notice requests are not consolidated.

Appendix

Docket No. (date filed)	Shipper name contract No.	Peak day [1] average annual	Points of		Start up date rate schedule	Related [2] dockets
			Receipt	Delivery		
CP90–1457–000	Marathon Oil Company Con. No. 2103	151,583 151,583 55,327,795	Offshore LA, TX, TX, LA	LA, TX FL, MS	3–8–90 ITS	ST90–2511–000
CP90–1458–000	OXY U.S.A. Company Con. No. 1903	30,900 30,900 11,278,500	TX	LA	3–28–90 ITS	ST90–3064–000
CP90–1459–000	NGC Transportation, Inc. Con. No. 4551	30,900 30,900 11,278,000	Offshore TX	MS	4–1–90 FTS	ST90–3087–000
CP90–1460–000	Centran Corporation Con. No. 2280	10,039 10,039 3,664,235	LA	LA, FL MS	3–7–90 ITS	ST90–2616–000
CP90–1461–000	Texaco Marketing Inc., Con. No. 1927	206,000 206,000 75,190,000	LA, MS	LA, FL AL, MS	4–16–90 ITS	ST90–2975–000

[1] Quantities are shown in MMBtu unless otherwise indicated.
[2] The CP docket corresponds to applicant's blanket transportation certificate. ST docket indicates that 120-day transportation service was reported in it.

7. K N Energy, Inc.

[Docket No. CP90–1501–000, Docket No. CP90–1502–000]

Take notice that K N Energy, Inc., P.O. Box 15265, Lakewood, Colorado 80215, (Applicant), filed in the above-referenced dockets prior notice requests pursuant to sections 157.205 and 284.223 of the Commission's Regulations under

the Natural Gas Act for authorization to transport natural gas on the behalf of various shippers under its blanket certificate issued in Docket No. CP89–1043–000, pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the requests that are on file with the Commission and open to public inspection.[5]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day, average day and annual volumes, and the initiation service dates and related ST docket numbers of the 120-day transactions under section 284.223 of the Commission's Regulations, has been provided by Applicant and is summarized in the attached appendix.

Applicant states that each of the proposed services would be provided under an executed transportation agreement, and that Applicant would charge the rates and abide by the terms and conditions of the referenced transportation rate schedules.

Comment date: July 27, 1990, in accordance with Standard Paragraph G at the end of this notice.

[5] These prior notice requests are not consolidated.

Appendix

Docket No. (date filed)	Shipper name	Peak day average day annual Mcf	Receipt [1] points	Delivery points	Contract date rate schedule service type	Related docket, start up date
CP90-1501-000 (6-7-90).	Kimball Energy Corporation.	25,000 25,000 9,125,000	Master Receipt List, TX	OK, TX	4-18-90, IT-1,2,3, Interruptible.	ST90-3082-000, 5-1-90
CP90-1502-000 (6-7-90).	OMNIgas, Inc	20,000 10,000 3,650,000	Master Receipt List	OK, TX	5-1-90, IT-1,2,3, Interruptible.	ST90-3083-000, 5-1-90

[1] The Master List is for all receipt points on the Buffalo Wallow System. Any state shown is for an additional requested receipt point.

8. Transwestern Pipeline Co., Stingray Pipeline Co., Northern Natural Gas Co.

Docket No. CP90–1488–000, Docket No. CP90–1490–000, Docket No. CP90–1495–000.

Take notice that the above referenced companies (Applicants) filed in the respective dockets prior notice requests pursuant to §§ 157.205 and 284.223 of the Commission's Regulations under the Natural Gas Act for authorization to transport natural gas on behalf of various shippers under the blanket certificates issued pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the prior notice requests which are on file with the Commission and open to public inspection.[6]

Information applicable to each transaction, including the identity of the shipper, the type of transportation service, the appropriate transportation rate schedule, the peak day , average day and annual volumes, and the initiating service dates and related docket numbers of the 120-day transactions under section 284.223 of the Commission's Regulations has been provided by the Applicants and is summarized in the attached appendix.

Applicants state that each of the proposed services would be provided under an executed transportation agreement, and that Applicants would charge the rates and abide by the terms and conditions of the referenced transportation rate schedules.

Comment date: July 27, 1990, in accordance with Standard Paragraph G at the end of this notice.

[6] These prior notice requests are not consolidated.

Appendix

Docket No. (date filed)	Applicant	Shipper	Peak day [1] average annual	Points of receipt	Points of delivery	Start up date (rate schedule)	Related [3] dockets
CP90-1488-000 (6-5-90)	Transwestern Pipeline Company, 1400 Smith Street, P.O. Box 1188, Houston, Texas 77251-1188.	Vesta Energy Co.	50,000 37,500 18,250,000	System	OK, TX	5-1-90 (ITS)	CP88-133-000, ST90-3088-000
CP90-1490-000 (6-5-90)	Stingray Pipeline Company, 701 East 22nd Street, Lombard, Illinois 60148.	Marathon Oil Co.	16,000 16,000 5,840,000	LA, TX	LA, TX	4-4-90 (ITS)	Order 509 [3], ST90-2910-000
CP90-1495-000 (6-5-90)	Northern Natural Gas Company, 1400 Smith Street, P.O. Box 1188, Houston, Texas 77251-1188.	VenGas Marketing Co.	10,000 7,500 3,650,000	TX	TX	5-1-90 (IT-1)	CP86-435-000, ST90-3031-000

[1] Quantities are shown in MMBtu unless otherwise indicated.
[2] The CP docket corresponds to applicant's blanket transportation certificate. If an ST docket is shown, 120-day transportation service was reported in it.
[3] Stingray states it commenced transportation under the blanket certificate issued by the Commission's Order No. 509

9. Great Lakes Gas Transmission Co.

[Docket Nos. CP87–164–007, CP87–464–008, CP88–307–007, CP88–310–005, CP88–599–004, CP88–826–002, CP88–719–001]

Take notice that on June 1, 1990, Great Lakes Gas Transmission Company (Great Lakes), 2100 Buhl Building, Detroit, Michigan 48226, filed in Docket Nos. CP87–164–007, CP87–464–008, CP88–307–007, CP88–310–005, CP88–599–004, CP88–826–002, and CP88–719–001 a petition to amend existing certificates of public convenience and necessity pursuant to section 7(c) of the Natural

Gas Act to extend the authorized terms of service, set forth in the petition which is on file with the Commission and open to public inspection.

Great Lakes seeks authorization to provide interruptible transportation service under separate case-specific section 7(c) certificate authority for seven of its existing interruptible service customers, whose services were previously authorized in the above referenced dockets. In each of the proceedings, the Commission limited the term of its authorization to the earlier of one year from the date of its last order in the proceedings, or the date that Great Lakes accepts a blanket certificate issued to it pursuant to part 284 of the Commission's Regulations. It is alleged that in this application, each of Great Lakes' seven customers has requested long-term, case specific, authorization that reflects their contractual arrangements with Great Lakes.

It is stated that the Commission has previously issued orders in the above referenced proceedings, authorizing Great Lakes to transport gas for Southeastern Michigan Gas Company; Ford Motor Company; Peoples Natural Gas Company, a Division of Utilicorp United Inc.; Northern States Power Company; Unicorp Energy, Inc. (Unicorp); Poco Petroleums, Ltd. (Poco), and Northern Minnesota Utilities, a Division of Utilicorp United Inc., on an interruptible basis. It is further stated that the term of the Commission authorization is limited to the earlier of one year from the date of the Commission authorization related to each service, or the date that Great Lakes accepts a blanket certificate issued by the Commission pursuant to part 284 of its Regulations (one-year limitation).

It is alleged that on September 29, 1989, Great Lakes filed an application for a blanket certificate of public convenience and necessity in Docket No. CP89–2198–000, requesting authorization to provide "open access", self-implementing transportation of natural gas for others, and pregranted authorization to abandon such self-implementing transportation services in accordance with the provision of section 284.221(d) of the Regulations. Great Lakes avers that it anticipates the issuance of a blanket certificates as of result of a settlement filed on May 18, 1990, in Docket No. CP89–2198–000, it requests an extension of the Commission authorizations related to the above noted services to October 31, 1991, and to "evergreen" such services, on a year-to-year basis thereafter.

Great Lakes contends that the Commission indicated in the above-referenced proceedings that it was appropriate to use the one-year limitation due to the concern about undue discrimination on the Great Lakes' system. Great Lakes alleges that since it would soon become an open access transporter, the basis of this concern would be eliminated.

It is stated that one of the transportation customers which receives interruptible service from Great Lakes, Unicorp, has requested that an existing point of interconnection between the facilities of Great Lakes and Michigan Gas Storage Company, located in Chippewa Township, Isabella County, Michigan (Chippewa Delivery Point) be added as a point of delivery under its current arrangements. The Chippewa Delivery Point is upstream of an existing delivery point for this service. There are no other changes to the existing contractual arrangements between Great Lakes and Unicorp. Great Lakes requests the Commission authorization for the addition of Chippewa Delivery Point.

Great Lakes also requires that the Commission issue an interim authorization prior to July 11, 1990, the date that the existing authorization for interruptible transportation for Poco terminates, if final authorization is issued by such date.

Comment date: July 3, 1990, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

10. ANR Pipeline Co. Indiana Ohio Pipeline Co. (Trunkline Gas Co.)

[Docket No. CP89–637–002, Docket No. CP88–178–002]

Take notice that on May 23, 1990, ANR Pipeline Company (ANR), 500 Renaissance Center, Detroit, Michigan, 48243 and Indiana Ohio Pipeline Company (Indiana Ohio) and Trunkline Gas Company (Trunkline) both at Post Office Box 1642, Houston, Texas 77251–1642 jointly filed in Docket Nos. CP89–637–002 and CP88–178–002 pursuant to section 7(c) of the Natural Gas Act (NGA), an amendment to their applications seeking authorizations to own and operate certain facilities in order to perform certain transportation services, all as more fully set forth in their amendment which is on file with the Commission and open to public inspection.

In this amendment, ANR seeks authority to operate, under section 7(c) of the NGA: (1) 37.8 miles of 30-inch pipeline which extends from an interconnection with the ANR mainline near Muncie, Indiana to Glen Karn, Ohio; (2) 5,400 horsepower of compression at the New Sulphur Springs compressor station in Henry County, Indiana; and, (3) four metering facilities in various counties in Ohio. ANR states that such facilities are currently being constructed pursuant to section 311 of the NGPA. According to ANR the 30-inch pipeline is estimated to be completed by mid-1990. ANR has provided no estimated completion date for the remaining facilities. These facilities are estimated to cost $41.4 million. ANR states that the proposed construction will be financed from funds on hand. Further, ANR requests that if for some reason the facilities to be constructed under section 311 are not completed by the issue date of an order granting such section 7(c) authority, the Commission also grant authority under section 7(c) for the construction of the remainder of the facilities.

In its amendment, Indiana Ohio requests that Trunkline, a sister-company of Indiana Ohio and a wholly-owned subsidiary of Panhandle Easter Pipeline Company (Panhandle), be substituted as the applicant in Docket No. CP88–178–002. Indiana Ohio states that such request for substitution should also be deemed by the Commissson as a request to withdraw its request for a blanket certificate authorizing self-implementing transportation that was made earlier in this docket.

Trunkline, as the new applicant in this amendment, requests authority under section 7(c) of the NGA to own and operate: (1) A 30-inch pipeline that is proposed to extend from an interconnection with the facilities of Panhandle in Grant County, Indiana, for 53.5 miles to a point near Glen Karn, Ohio: (2) 5,000 horsepower of compression at the Panhandle interconnection; (3) a metering facility at the Panhandle interconnection; and, (4) a meter station at Glen Karn, Ohio. Trunkline states that these faciliies will be constructed pursuant to Section 311 of the NGPA. Trunkline estimates that the 30-inch pipeline will be completed in mid-1990, but provides no estimate as to the completion date of the remaining facilities. Trunkline states that these facilities have an estimated cost of $44.3 million and will be financed from funds on hand and short-term bank borrowing. Trunkline also requests that if for some reason the facilities to be constructed under section 311 are not completed by the issue date of an order granting such section 7(c) authority conversion, the Commission also grant authority under section 7(c) for the construction of the remainder of the facilities.

ANR and Trunkline also propose, pursuant to section 7(c), to jointly own: (1) A 36-inch pipeline which is to extend from an interconnection with the two 30-inch pipelines described above at their terminus in Glen Karn, Ohio, to a point 60.7 miles away in Lebanon, Ohio where it interconnects with the facilities of Columbia Gas Transmissison Corporation, CNG Transmission Corporation and Texas Eastern Transmission Corporation; and, (2) a meter station at Lebanon, Ohio. ANR will construct this pipeline and meter station under section 311 authority at an estimated cost of $77.1 million. Trunkline seeks authority under section 7(c) of the NGA to operate this pipeline and meter station after construction is completed by ANR. The capacity of this line is 800 MMcf per day, which under the tenants-in-common proposal made in by ANR and Trunkline, results in a share of the capacity of 400 MMcf per day each.

ANR proposes to utilize its portion of the capacity in the pipeline to provide the following services: (1) 138 MMcf per day, plus 4.7 MMcf per day fuel, for various customers in the ANR Phase III Northeast Project, as described in Docket No. CP89–637–001; and, (2) 30.8 MMcf per day to Dayton Power and Light at three delivery points in Ohio. ANR states that the rest of their portion will be used to meet transportation requests in ANR's transportation queue which, according to ANR, are in excess of the remaining capacity.

Trunkline states that it is currently finalizing commitments for firm service of 150 MMcf per day and that it has entered into a precedent agreement to provide 150 MMcf per day of interruptible service. Trunkline also states that additional requests for interruptible transportation, which are on Trunkline's interruptible transportation queue, are substantial and collectively exceed the anticipated capacity of the Lebanon lateral.

Comment date: July 1990, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 90–14193 6–19–90; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. ST90–2452–000 through ST90–2791–000]

Natural Gas Pipeline Co. of America; Self-Implementing Transactions

June 12, 1990.

Take notice that the following transactions have been reported to the Commission as being implemented pursuant to part 284 of the Commission's regulations, sections 311 and 312 of the Natural Gas Policy Act of 1978 (NGPA) and section 5 of the Outer Continental Shelf Lands Act.[1]

The "Recipient" column in the following table indicates the entity receiving or purchasing the natural gas in each transaction.

The "Part 284 Subpart" column in the following table indicates the type of transaction.

A "B" indicates transportation by an interstate pipeline on behalf of an intrastate pipeline or a local distribution company pursuant to § 284.102 of the Commission's regulations and section 311(a)(1) of the NGPA.

A "C" indicates transportation by an intrastate pipeline on behalf of an interstate pipeline or a local distribution company served by an interstate pipeline pursuant to § 284.122 of the Commission's regulations and section 311(a)(2) of the NGPA.

A "D" indicates a sale by an intrastate pipeline to an interstate pipeline or a local distribution company served by an interstate pipeline pursuant to § 284.142 of the Commission's Regulations and section 311(b) of the NGPA. Any interested person may file a complaint concerning such sales pursuant to § 284.147(d) of the Commission's regulations.

An "E" indicates an assignment by an intrastate pipeline to and interstate pipeline or local distribution company pursuant to § 284.163 of the Commission's regulations and section 312 of the NGPA.

A "G" indicates transportation by an interstate pipeline on behalf of another interstate pipeline pursuant to § 284.222 and a blanket certificate issued under § 284.221 of the Commission's regulations.

A "G–S" indicates transportation by interstate pipelines on behalf of shippers other than interstate pipelines pursuant to § 284.223 and a blanket certificate issued under § 284.221 of the Commission's regulations.

A "G–LT" or "G–LS" indicates transportation, sales or assignments by a local distribution company on behalf of or to an interstate pipeline or local distribution company pursuant to a blanket certificate issued under § 284.224 of the Commission's regulations.

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[1] Notice of a transaction does not constitute a determination that the terms and conditions of the proposed service will be approved or that the noticed filing is in compliance with the Commission's regulations.

A "G–HT" or "G–HS" indicates transportation, sales or assignments by a Hinshaw Pipeline pursuant to a blanket certificate issued under § 284.224 of the Commission's regulations.

A "K" indicates transportation of natural gas on the Outer Continental Shelf by an interstate pipeline on behalf of another interstate pipeline pursuant to § 284.303 of the Commission's regulations.

A "K–S" indicates transportation or natural gas on the Outer Continental Shelf by an intrastate pipeline on behalf of shippers other than interstate pipelines pursuant to § 284.303 of the Commission's regulations.

Lois D. Cashell,

Secretary.

Docket No. [1]	Transporter/seller	Recipient	Date filed	Part 284 subpart	Estimated maximum daily quantity [2]
ST90-2452	Natural Gas Pipeline Co. of America	Dow Pipeline Co	04-02-90	B	42,000
ST90-2453	Mississippi River Transmission Corp	Llano, Inc	04-02-90	B	200,000
ST90-2454	Nycotex Gas Transport	Polaris Corp	04-02-90	C	15,000
ST90-2455	Colorado Interstate Gas Co	Anadarko Trading Co	04-02-90	G-S	25,000
ST90-2456	Panhandle Eastern Pipe Line Co	Northern Indiana Fuel & Light Co	04-02-90	B	2,405
ST90-2457	Trunkline Gas Co	NGC Intrastate Pipeline Co	04-02-90	B	100,000
ST90-2458	Panhandle Eastern Pipe Line Co	Anadarko Trading Co	04-02-90	G-S	1,610
ST90-2459	Panhandle Eastern Pipe Line Co	Enron Gas Marketing, Inc	04-02-90	G-S	5,000
ST90-2460	Panhandle Eastern Pipe Line Co	American Central Gas Marketing Co	04-02-90	G-S	40,000
ST90-2461	Panhandle Eastern Pipe Line Co	Amgas, Inc	04-02-90	G-S	2,800
ST90-2462	Panhandle Eastern Pipe Line Co	BP Oil Co	04-02-90	G-S	20,000
ST90-2463	Panhandle Eastern Pipe Line Co	Quincy Soybean Co	04-02-90	G-S	5,600
ST90-2464	Panhandle Eastern Pipe Line Co	Indiana Gas Co	04-02-90	B	50,000
ST90-2465	Panhandle Eastern Pipe Line Co	LL & E Gas Marketing, Inc	04-02-90	G-S	50,000
ST90-2466	Panhandle Eastern Pipe Line Co	Indiana Gas Co	04-02-90	B	3,000
ST90-2467	Panhandle Eastern Pipe Line Co	Entrade Corp	04-02-90	G-S	100,000
ST90-2468	Panhandle Eastern Pipe Line Co	Amgas, Inc	04-02-90	G-S	210
ST90-2469	Trunkline Gas Co	Memphis Light, Gas and Water Division	04-02-90	B	2,000
ST90-2470	Trunkline Gas Co	Memphis Light, Gas and Water Division	04-02-90	B	200,000
ST90-2471	Transcontinental Gas Pipe Line Corp	Piedmont Natural Gas Co	04-02-90	B	1,332,450
ST90-2472	Transcontinental Gas Pipe Line Corp	Orange and Rockland Utilities, Inc	04-02-90	B	6,000
ST90-2473	Texas Gas Transmission Corp	NGC Intrastate Pipeline Co	04-02-90	B	300,000
ST90-2474	Texas Gas Transmission Corp	Continental Natural Gas, Inc	04-02-90	G-S	50,000
ST90-2475	Columbia Gulf Transmission Co	Monterey Pipeline Co	04-03-90	B	50,000
ST90-2476	Valero Transmission, L.P	Tennessee Gas Pipeline Co	04-03-90	C	11,000
ST90-2477	Valero Transmission, L.P	Trunkline Gas Co	04-03-90	C	9,000
ST90-2478	Valero Transmission, L.P	Trunkline Gas Co	04-03-90	C	5,000
ST90-2479	Delhi Gas Pipeline Corp	Texas Eastern Transmission Corp	04-03-90	C	2,000
ST90-2480	Delhi Gas Pipeline Corp	Mississippi River Transmission Corp	04-03-90	C	2,000
ST90-2481	Northern Natural Gas Co	Exxon Corp	04-04-90	G-S	100,000
ST90-2482	Tennessee Gas Pipeline Co	Acacia Gas Corp	04-04-90	G-S	25,000
ST90-2483	Lone Star Gas Co	Phillips Gas Pipeline Co	04-04-90	C	25,000
ST90-2484	Transcontinental Gas Pipe Line Corp	Fort Hill Natural Gas Authority	04-04-90	B	22,331
ST90-2485	Louisiana-Nevada Transit Co	Enmark Gas Corp	04-04-90	G-S	5,000
ST90-2486	Northern Border Pipeline Co	Northern Natural Gas Co	04-04-90	G	252,000
ST90-2487	Utah Gas Service Co	Northwest Pipeline Corp	04-05-90	C	1,300
ST90-2488	Natural Gas Pipeline Co. of America	Union Exploration Partners, Ltd	04-05-90	G-S	20,000
ST90-2489	Natural Gas Pipeline Co. of America	Tex/Con Gas Pipeline Co	04-05-90	B	100,000
ST90-2490	Natural Gas Pipeline Co. of America	United Texas Transmission Co	04-05-90	B	30,000
ST90-2491	Westar Transmission Co	El Paso Natural Gas Co., et al	04-06-90	C	20,000
ST90-2492	Equitrans, Inc	Texas-Ohio Gas, Inc	04-05-90	G-S	7,840
ST90-2493	Equitrans, Inc	Catamount Natural Gas, Inc	04-05-90	G-S	48,543
ST90-2494	Equitrans, Inc	Paragon Gas Corp	04-05-90	G-S	9,800
ST90-2495	Equitrans, Inc	Ashton Energy Co	04-05-90	G-S	24,500
ST90-2496	Gulf Energy Pipeline Co	Tennessee Gas Pipeline Co	04-06-90	C	15,000
ST90-2497	PSI Gas Systems, Inc	Panhandle Eastern Pipeline Co., et al	04-06-90	C	2,940
ST90-2498	Texas Eastern Transmission Corp	Brooklyn Union Gas Co	04-06-90	B	80,000
ST90-2499	Mississippi River Transmission Corp	Bishop Pipeline Corp	04-06-90	G-S	6,000
ST90-2500	Mississippi River Transmission Corp	Gastrak Corp	04-06-90	G-S	30,000
ST90-2501	Mississippi River Transmission Corp	Continental Natural Gas, Inc	04-06-90	G-S	100,000
ST90-2502	Mississippi River Transmission Corp	J-W Gathering Co	04-06-90	B	100,000
ST90-2503	Mississippi River Transmission Corp	Vesta Energy Co	04-06-90	G-S	100,000
ST90-2504	Mississippi River Transmission Corp	Consolidated Fuel Corp	04-06-90	G-S	1,030
ST90-2505	Westar Transmission Co	Northern Natural Gas Co	04-06-90	C	1,500
ST90-2506	Williston Basin Interstate P/L Co	MGTC, Inc	04-09-90	B	277,479
ST90-2507	Enserch Gas Transmission Co	Trunkline Gas Co	04-09-90	C	50,000
ST90-2508	Tennessee Gas Pipeline Co	Columbia Gas Transmission Corp	04-09-90	G	102,600
ST90-2509	Natural Gas Pipeline Co. of America	Transamerican Gas Transmission Corp	04-09-90	B	100,000
ST90-2510	Natural Gas Pipeline Co. of America	Interstate Power Co	04-09-90	B	20,000
ST90-2511	United Gas Pipe Line Co	Exxon Corp	04-09-90	G-S	103,000
ST90-2512	United Gas Pipe Line Co	Phibro Distributors Corp	04-09-90	G-S	309,000
ST90-2513	Texas Eastern Transmission Corp	Access Energy Pipeline Corp	04-09-90	B	115,000
ST90-2514	Transcontinental Gas Pipe Line Corp	North Carolina Gas Service Co	04-10-90	B	27,879
ST90-2515	Transcontinental Gas Pipe Line Corp	Washington Gas Light Co	04-10-90	B	73,717
ST90-2516	Kansas Power and Light Co	Semco Energy Services, Inc	04-10-90	D	3,150
ST90-2517	United Gas Pipeline Co	Exxon Corp	04-10-90	G-S	103,000
ST90-2518	Carnegie Natural Gas Co	Carnegie Natural Gas Sales, Inc	04-10-90	G-S	3,000
ST90-2519	Mississippi River Transmission Corp	Archer Daniels Midland Co	04-10-90	G-S	3,100
ST90-2520	Mississippi River Transmission Corp	Entrade Corp	04-10-90	G-S	20,000

Docket No. [1]	Transporter/seller	Recipient	Date filed	Part 284 subpart	Estimated maximum daily quantity [2]
ST90-2521	El Paso Natural Gas Co	Cominco American, Inc	04-10-90	G-S	49,995
ST90-2522	Natural Gas Pipeline Co. of America	Tennessee Gas Pipeline Co	04-11-90	G-S	50,000
ST90-2523	Natural Gas Pipeline Co. of America	Elf Aquitaine Operating Inc	04-11-90	G	150,000
ST90-2524	Northern Natural Gas Co	Associated Intrastate Pipeline Co	04-11-90	B	250,000
ST90-2525	Northern Natural Gas Co	Access Energy Corp	04-11-90	G-S	20,000
ST90-2526	Transcontinental Gas Pipe Line Corp	Commonwealth Gas Pipeline Corp	04-11-90	B	172,902
ST90-2527	Transcontinental Gas Pipe Line Corp	Commonwealth Gas Pipeline Corp	04-11-90	B	64,500
ST90-2528	Northern Border Pipeline Co	Interstate Power Co	04-11-90	B	20,000
ST90-2529	Northern Border Pipeline Co	Iowa Electric Light & Power Co	04-11-90	B	150,000
ST90-2530	ANR Pipeline Co	Michigan Gas Utilities Co	04-12-90	B	100,000
ST90-2531	ANR Pipeline Co	Louisiana Intrastate Gas Corp	04-12-90	B	1,400
ST90-2532	ANR Pipeline Co	Alliance Operating Corp	04-12-90	G-S	500
ST90-2533	ANR Pipeline Co	Tarpon Gas Marketing Ltd	04-12-90	G-S	150,000
ST90-2534	ANR Pipeline Co	Coastal States Gas Transmission Co	04-12-90	B	125,000
ST90-2535	ANR Pipeline Co	Mobil Vanderbilt-Beaumont Pipeline Co	04-12-90	B	100,000
ST90-2536	Tennessee Gas Pipeline Co	Western Gas marketing USA Ltd	04-12-90	G-S	51,550
ST90-2537	Tennessee Gas Pipeline Co	Texas Eastern Transmission Corp	04-12-90	G	1,000,000
ST90-2538	Tennessee Gas Pipeline Co	Creole Gas Pipeline Co	04-12-90	B	1,000,000
ST90-2539	Tennessee Gas Pipeline Co	City of Burns	04-12-90	B	1,000,000
ST90-2540	Northern Natural Gas Co	American Central Gas Cos., Inc	04-12-90	G-S	200,000
ST90-2541	Natural Gas Pipeline Co. of America	Chevron U.S.A., Inc	04-12-90	G-S	100,000
ST90-2542	Texas Eastern Transmission Corp	Public Service Electric and Gas Co	04-12-90	B	15,000
ST90-2543	Transok, Inc	Phillips Gas Pipeline Co	04-12-90	C	50,000
ST90-2544	El Paso Natural Gas Co	American Hunter Exploration, Ltd	04-13-90	G-S	154,500
ST90-2545	Transcontinental Gas Pipe Line Corp	City of Richmond	04-12-90	B	20,000
ST90-2546	Transcontinental Gas Pipe Line Corp	Washington Gas Light Co	04-12-90	B	400,000
ST90-2547	Delhi Gas Pipeline Corp	Transwestern Pipeline Co	04-13-90	C	80,000
ST90-2548	Delhi Gas Pipeline Corp	Panhandle Eastern Pipe Line Co	04-13-90	C	10,000
ST90-2549	Delhi Gas Pipeline Corp	New Jersey Natural Gas Co	04-13-90	C	15,000
ST90-2550	Delhi Gas Pipeline Corp	Panhandle Eastern Pipe Line Co	04-13-90	C	5,000
ST90-2551	Delhi Gas Pipeline Corp	Mississippi River Transmission Corp	04-13-90	C	5,000
ST90-2552	Delhi Gas Pipeline Corp	El Paso Natural Gas Co	04-13-90	C	50,000
ST90-2553	Delhi Gas Pipeline Corp	Northern Natural Gas Co	04-13-90	C	7,000
ST90-2554	Delhi Gas Pipeline Corp	Transwestern Pipeline Co	04-13-90	C	30,000
ST90-2555	Delhi Gas Pipeline Corp	Mississippi River Transmission Corp	04-13-90	C	1,000
ST90-2556	Alabama-Tennessee Natural Gas Co	Sonat Marketing Co	04-13-90	G-S	202,500
ST90-2557	Alabama-Tennessee Natural Gas Co	Louis Dreyfuss Energy Corp	04-13-90	G-S	75,000
ST90-2558	Williston Basin Interstate P/L Co	Cody Gas Co	04-13-90	B	17,400
ST90-2559	Williston Basin Interstate P/L Co	Quivira Gas Co	04-13-90	B	184,100
ST90-2560	Williston Basin Interstate P/L Co	Exxon Corp	04-13-90	G-S	45,000
ST90-2561	Texas Gas Transmission Corp	NGC Transportation, Inc	04-16-90	G-S	300,000
ST90-2562	Texas Gas Transmission Corp	Flynn Enterprises, Inc	04-16-90	B	210
ST90-2563	Texas Gas Transmission Corp	Polaris Pipeline Co	04-16-90	G-S	100,000
ST90-2564	Texas Gas Transmission Corp	Centran Corp	04-16-90	G-S	50,000
ST90-2565	Natural Gas Pipeline Co. of America	Central Illinois Light Co	04-16-90	B	50,000
ST90-2566	Equitrans, Inc	Phoenix Diversified Ventures, Inc	04-16-90	G-S	58,800
ST90-2567	Equitrans, Inc	Endevco Marketing Co	04-16-90	G-S	9,800
ST90-2568	Mississippi River Transmission Corp	Santanna Natural Gas Corp	04-16-90	G-S	100,000
ST90-2569	Mississippi River Transmission Corp	Louis Dreyfuss Energy Corp	04-16-90	G-S	100,000
ST90-2570	Mississippi River Transmission Corp	V.H.C. Gas System, L.P.	04-16-90	G-S	200,000
ST90-2571	Mississippi River Transmission Corp	Arco Natural Gas Marketing, Inc	04-16-90	G-S	100,000
ST90-2578	Dow Pipeline Co	Phillips Gas Pipeline Co	04-17-90	C	50,000
ST90-2579	Dow Pipeline Co	TPC Transmission, Inc	04-17-90	C	25,000
ST90-2580	Dow Pipeline Co	Blue Dolphin Pipe Line Co	04-17-90	C	20,000
ST90-2581	Delhi Gas Pipeline Corp	Tennessee Gas Pipeline Co	04-17-90	C	2,000
ST90-2582	Red River Pipeline	El Paso Natural Gas Co	04-17-90	C	50,000
ST90-2583	Red River Pipeline	El Paso Natural Gas Co	04-17-90	C	50,000
ST90-2584	Red River Pipeline	El Paso Natural Gas Co	04-17-90	C	250,000
ST90-2585	Red River Pipeline	El Paso Natural Gas Co	04-17-90	C	50,000
ST90-2586	Sabine Pipe Line Co	Memphis Light, Gas and Water Division	04-17-90	B	150,000
ST90-2587	Natural Gas Pipeline Co. of America	ANR Pipeline Co	04-18-90	G	13,700
ST90-2588	Natural Gas Pipeline Co. of America	Seagull Marketing Services, Inc	04-18-90	G-S	100,000
ST90-2589	Tennessee Gas Pipeline Co	Enserch Gas Co	04-18-90	G-S	100,000
ST90-2590	Valero Transmission, L.P.	Natural Gas Pipeline Co. of America	04-18-90	C	2,000
ST90-2591	Green Canyon Pipe Line Co	Union Exploration Partners, Ltd	04-18-90	G-S	8,000
ST90-2592	Transcontinental Gas Pipe Line Corp	Transco Energy Marketing Co	04-18-90	G-S	10,000
ST90-2593	Transcontinental Gas Pipe Line Corp	Arco Oil & Gas Co	04-18-90	G-S	25,000
ST90-2594	United Gas Pipe Line Co	Gulf South Transmission Co., et al	04-18-90	B	14,935
ST90-2595	United Gas Pipe Line Co	Texas Gas Marketing, Inc	04-18-90	G-S	103,000
ST90-2596	Transwestern Pipeline Co	BHP Gas Marketing Co	04-18-90	G-S	50,000
ST90-2597	Transwestern Pipeline Co	Access Energy Corp	04-18-90	B	8,000
ST90-2598	Transwestern Pipeline Co	Sun Operating Limited Partnership	04-18-90	G-S	40,000
ST90-2599	Williams Natural Gas Co	Atchison Pipeline Co., L.P.	04-18-90	B	75,000
ST90-2600	Northwest Pipeline Corp	Williams Gas Marketing Co	04-18-90	G-S	10,000
ST90-2601	Northwest Pipeline Corp	Phillips Petroleum Co	04-18-90	G-S	70,000
ST90-2602	Northern Natural Gas Co	Adobe/Midland Joint Venture	04-18-90	G-S	100,000
ST90-2603	Northern Natural Gas Co	Phibro Distributors Corp	04-18-90	G-S	300,000
ST90-2604	Northern Natural Gas Co	Phillips Petroleum Co	04-18-90	G-S	40,000
ST90-2605	Northern Natural Gas Co	Natgas U.S. Inc	04-18-90	G-S	75,000
ST90-2606	Northern Natural Gas Co	Anadarko Trading Co	04-18-90	G-S	100,000

Docket No. [1]	Transporter/seller	Recipient	Date filed	Part 284 subpart	Estimated maximum daily quantity [2]
ST90-2607	Northern Natural Gas Co	FMI Hydrocarbons Co	04-18-90	G-S	10,000
ST90-2608	Northern Natural Gas Co	Texaco Gas Marketing, Inc	04-18-90	G-S	100,000
ST90-2609	Northern Natural Gas Co	Hutchinson Utility Commission	04-18-90	B	600
ST90-2610	Northern Natural Gas Co	Peoples Natural Gas Co	04-18-90	B	50
ST90-2611	Delhi Gas Pipeline Corp	San Diego Gas & Electric Co	04-19-90	C	90,000
ST90-2612	Delhi Gas Pipeline Corp	Transwestern Pipeline Co	04-19-90	C	10,000
ST90-2613	Delhi Gas Pipeline Corp	Mississippi River Transmission Corp	04-19-90	C	10,000
ST90-2614	Delhi Gas Pipeline Corp	Transwestern Pipeline Co	04-19-90	C	10,000
ST90-2615	United Gas Pipe Line Co	Graham Energy Marketing Co	04-19-90	G-S	123,600
ST90-2616	United Gas Pipe Line Co	Centran Corp	04-19-90	G-S	10,039
ST90-2617	United Gas Pipe Line Co	Heath Petra Resources, Inc	04-19-90	G-S	20,600
ST90-2618	United Gas Pipe Line Co	Texaco Gas Marketing, Inc	04-19-90	G-S	51,500
ST90-2619	Tennessee Gas Pipeline Co	Longhorn Pipeline Co	04-19-90	B	696,488
ST90-2620	United Gas Pipe Line Co	Texaco Gas Marketing, Inc	04-20-90	G-S	103,000
ST90-2621	United Gas Pipe Line Co	Mobil Natural Gas, Inc	04-20-90	G-S	51,500
ST90-2622	United Gas Pipe Line Co	Texaco Gas Marketing, Inc	04-20-90	G-S	360,500
ST90-2623	United Gas Pipe Line Co	Texaco Gas Marketing, Inc	04-20-90	G-S	103,000
ST90-2624	Mississippi River Transmission Corp	Tennessee Gas Pipeline Co	04-20-90	G	150,000
ST90-2625	Valero Transmission, L.P.	Texas Eastern Gas Pipeline Co	04-20-90	C	5,000
ST90-2626	Tennessee Gas Pipeline Co	Meridian Oil Inc	04-20-90	G-S	200,000
ST90-2627	Tennessee Gas Pipeline Co	United Gas Pipe Line Co	04-20-90	G	307,500
ST90-2628	Tennessee Gas Pipeline Co	Centran Corp	04-20-90	G-S	250,000
ST90-2629	Channel Industries Gas Co	Tennessee Gas Pipeline Co., et al	04-20-90	C	15,000
ST90-2630	Natural Gas Pipeline Co. of America	Centran Corp	04-23-90	G-S	50,000
ST90-2631	Natural Gas Pipeline Co. of America	Phillips Petroleum Co	04-23-90	G-S	25,000
ST90-2632	Midwestern Gas Transmission Co	Northern Illinois Gas Co	04-23-90	B	100,000
ST90-2633	Northwest Pipeline Corp	Western Gas Processors	04-23-90	G-S	4,000
ST90-2634	Northwest Pipeline Corp	Pacific Gas and Electric Co	04-23-90	B	6,000
ST90-2635	Northwest Pipeline Corp	Internationaler Energie Fonds, GMBH	04-23-90	G-S	1,000
ST90-2636	Louisiana Resources Co	Florida Gas Transmission Co	04-23-90	C	50,000
ST90-2637	Trunkline Gas Co	American Central Gas Marketing Co	04-23-90	G-S	25,000
ST90-2638	Trunkline Gas Co	Mississippi River Transmission Corp	04-23-90	G	30,000
ST90-2639	Trunkline Gas Co	PSI, Inc	04-23-90	G-S	100,000
ST90-2640	Trunkline Gas Co	Brooklyn Interstate Natural Gas Corp	04-23-90	G-S	80,000
ST90-2641	Trunkline Gas Co	Coastal Gas Marketing Co	04-23-90	G-S	100,000
ST90-2642	Trunkline Gas Co	Unicorp Energy, Inc	04-23-90	G-S	150,000
ST90-2643	Columbia Gulf Transmission Co	Enmark Gas Corp	04-23-90	G-S	50,000
ST90-2644	Panhandle Eastern Pipe Line Co	Coastal Gas Marketing Co	04-23-90	G-S	300,000
ST90-2645	Trunkline Gas Co	Coastal Gas Marketing Co	04-23-90	G-S	100,000
ST90-2646	Panhandle Eastern Pipe Line Co	Consumers Power Co	04-23-90	B	24,900
ST90-2647	Trunkline Gas Co	Continental Natural Gas, Inc	04-23-90	G-S	50,000
ST90-2648	Texas Gas Transmission Corp	Phibro Distributors Corp	04-24-90	G-S	200,000
ST90-2649	Enogex Inc	ANR Pipeline Co	04-24-90	C	50,000
ST90-2650	Enogex Inc	Panhandle Eastern Pipe Line Co	04-24-90	C	50,000
ST90-2651	ANR Pipeline Co	Texpar Energy, Inc	04-24-90	G-S	50,000
ST90-2652	ANR Pipeline Co	Ohio Valley Gas Corp	04-24-90	B	2,000
ST90-2653	ANR Pipeline Co	Northern Indiana Fuel & Light Co	04-24-90	B	12,000
ST90-2654	ANR Pipeline Co	Beloit Box Board Co. 24	04-24-90	G-S	280
ST90-2655	ANR Pipeline Co	Kimberly-Clark Corp	04-24-90	G-S	4,030
ST90-2656	ANR Pipeline Co	James River Corp	04-24-90	G-S	1,800
ST90-2657	ANR Pipeline Co	NGC Intrastate Pipeline Co	04-24-90	B	200,000
ST90-2658	ANR Pipeline Co	Hall-Houston Oil Co	04-24-90	G-S	8,000
ST90-2659	ANR Pipeline Co	West Ohio Gas Co	04-24-90	B	3,900
ST90-2660	ANR Pipeline Co	Coastal States Gas Transmission Co	04-24-90	B	500,000
ST90-2661	ANR Pipeline Co	Madison Gas & Electric Co	04-24-90	B	40,000
ST90-2662	Enogex, Inc	El Paso Natural Gas Co	04-25-90	C	50,000
ST90-2663	Enogex, Inc	Arkla Energy Resources	04-25-90	C	50,000
ST90-2664	Natural Gas Pipeline Co. of America	Minnegasco, Inc	04-25-90	B	12,750
ST90-2665	Natural Gas Pipeline Co. of America	Columbia Gas Transmission Corp	04-25-90	G	200,000
ST90-2666	Natural Gas Pipeline Co. of America	Northern Illinois Gas Co	04-25-90	B	3,000
ST90-2667	Natural Gas Pipeline Co. of America	Coastal Gas Marketing Co	04-25-90	G-S	200,000
ST90-2668	Enogex Inc	ANR Pipeline Co	04-25-90	C	50,000
ST90-2669	Tex/Con Gas Pipeline Co	El Paso Natural Gas Co., et al	04-25-90	C	10,000
ST90-2670	Panhandle Eastern Pipe Line Co	Kerr-McGee Corp	04-25-90	G-S	5,000
ST90-2671	Panhandle Eastern Pipe Line Co	TXO Production Co	04-25-90	G-S	500
ST90-2672	Panhandle Eastern Pipe Line Co	Sunnybrook Transmission Inc	04-25-90	G-S	3,000
ST90-2673	Panhandle Eastern Pipe Line Co	Semco Energy Services, Inc	04-25-90	G-S	50,000
ST90-2674	Trunkline Gas Co	Transamerican Gas Transmission Corp	04-25-90	B	200,000
ST90-2675	Trunkline Gas Co	Llano, Inc	04-25-90	B	75,000
ST90-2676	Trunkline Gas Co	Steller Gas Co	04-25-90	B	50,000
ST90-2677	Trunkline Gas Co	Memphis Light, Gas and Water Division	04-25-90	B	39,000
ST90-2678	Trunkline Gas Co	Coastal States Gas Transmission Co	04-25-90	B	150,000
ST90-2679	Equitrans, Inc	Columbia Gas of Pennsylvania, Inc	04-25-90	G-S	29,400
ST90-2680	Transamerican Gas Transmission Corp	United Gas Pipe Line Co	04-25-90	C	10,000
ST90-2681	Transamerican Gas Transmission Corp	Trunkline Gas Co	04-25-90	C	15,400
ST90-2682	Transamerican Gas Transmission Corp	Northern Illinois Gas Co	04-25-90	C	27
ST90-2683	Transamerican Gas Transmission Corp	Northern Illinois Gas Co	04-25-90	C	20
ST90-2684	Transamerican Gas Transmission Corp	Northern Illinois Gas Co	04-25-90	C	72
ST90-2685	Transamerican Gas Transmission Corp	Northern Illinois Gas Co	04-25-90	C	30
ST90-2686	Transamerican Gas Transmission Corp	Northern Illinois Gas Co	04-25-90	C	40

Docket No. [1]	Transporter/seller	Recipient	Date filed	Part 284 subpart	Estimated maximum daily quantity [2]
ST90-2687	Transamerican Gas Transmission Corp	North Shore Gas Co	04-25-90	C	8
ST90-2688	Transamerican Gas Transmission Corp	Midwestern Gas Transmission Co	04-25-90	C	15,000
ST90-2689	Transamerican Gas Transmission Corp	Texas Eastern Transmission Corp	04-25-90	C	100,000
ST90-2690	Transamerican Gas Transmission Corp	Natural Gas Pipeline Co. of America	04-25-90	C	12,000
ST90-2691	Transamerican Gas Transmission Corp	Tennessee Gas Pipeline Co	04-25-90	C	20,000
ST90-2692	Transamerican Gas Transmission Corp	United Gas Pipe Line Co	04-25-90	C	31,000
ST90-2693	Transamerican Gas Transmission Corp	Natural Gas Pipeline Co. of America	04-25-90	C	4,966
ST90-2694	Transamerican Gas Transmission Corp	City of New Roads	04-25-90	C	200
ST90-2695	Transamerican Gas Transmission Corp	Trunkline Gas Co	04-25-90	C	10,722
ST90-2696	Transamerican Gas Transmission Corp	Central Illinois Public Service Co	04-25-90	C	80
ST90-2697	Natural Gas Pipeline Co. of America	Cabot Oil & Gas Marketing Corp	04-26-90	G-S	40,000
ST90-2698	Natural Gas Pipeline Co. of America	Moraine Pipeline Co	04-26-90	B	150,000
ST90-2699	Natural Gas Pipeline Co. of America	Cabot Oil & Gas Marketing Corp	04-26-90	G-S	7,500
ST90-2700	Northern Natural Gas Co	NGC Transportation, Inc	04-26-90	G-S	25,000
ST90-2701	Northern Natural Gas Co	NGC Transportation, Inc	04-26-90	G-S	60,000
ST90-2702	Northern Natural Gas Co	Transok Ventures Co	04-26-90	G-S	80,000
ST90-2703	High Island Offshore System	Superior Natural Gas Corp	04-26-90	K-S	80,000
ST90-2704	High Island Offshore System	PSI, Inc	04-26-90	K-S	1,435,000
ST90-2705	High Island Offshore System	Hadson Gas Systems, Inc	04-26-90	K-S	200,000
ST90-2706	High Island Offshore System	Stellar Gas Co	04-26-90	K-S	100,000
ST90-2707	High Island Offshore System	Tenngasco Corp	04-26-90	K-S	333,500
ST90-2708	High Island Offshore System	Excel Gas Marketing, Inc	04-26-90	K-S	870,000
ST90-2709	High Island Offshore System	Elf Exploration, Inc	04-26-90	K-S	150,000
ST90-2710	High Island Offshore System	Union Exploration partners, Ltd	04-26-90	K-S	63,544
ST90-2711	High Island Offshore System	Edisto Resources Corp	04-26-90	K-S	71,500
ST90-2712	United Gas Pipe Line Co	Texaco Gas Marketing, Inc	04-26-90	G-S	41,200
ST90-2713	Northwest Pipeline Co	Paiute Pipeline Co	04-26-90	G	10,000
ST90-2714	Williston Basin Interstate P/L Co	Montana-Dakota Utilities Co	04-25-90	B	111,449
ST90-2715	Natural Gas Pipeline Co. of America	Acadian Gas Pipeline System	04-27-90	B	200,000
ST90-2716	Natural Gas Pipeline Co. of America	Access Energy Pipeline Corp	04-27-90	B	3,000
ST90-2717	Natural Gas Pipeline Co. of America	Tex/Con Gas Pipeline Co	04-27-90	B	150,000
ST90-2718	Natural Gas Pipeline Co. of America	Minnegasco, Inc	04-27-90	B	150,000
ST90-2719	El Paso Natural Gas Co	West Texas Gas, Inc	04-27-90	B	412
ST90-2720	Tennessee Gas Pipeline Co	Columbia Gas Transmission Corp	04-27-90	G	200,000
ST90-2721	Tennessee Gas Pipeline Co	Sipco Gas Transmission Corp	04-27-90	B	40,000
ST90-2722	Southern Natural Gas Co	Enjet Natural Gas, Inc	04-27-90	G-S	25,000
ST90-2723	Southern Natural Gas Co	South Georgia Natural Gas Co	04-27-90	G	3,000
ST90-2724	Southern Natural Gas Co	City of Fort Valley	04-27-90	B	6,000
ST90-2725	Colorado Interstate Gas Co	Texas Industrial Energy Co	04-27-90	B	147,000
ST90-2726	Colorado Interstate Gas Co	Associated Intrastate Pipeline Co	04-27-90	B	145,000
ST90-2727	Colorado Interstate Gas Co	Associated Intrastrate Pipeline Co	04-27-90	B	40,000
ST90-2728	Colorado Interstate Gas Co	Llano, Inc	04-27-90	B	500
ST90-2729	Colorado Interstate Gas Co	Enron Industrial Natural Gas Co	04-27-90	B	50,000
ST90-2730	High Island Offshore System	Coastal Gas Marketing Co	04-27-90	K-S	1,225,000
ST90-2731	Southern Natural Gas Co	City of Dyersburg, et al	04-27-90	B	120,000
ST90-2732	Southern Natural Gas Co	City of Cartersville	04-27-90	B	600
ST90-2733	High Island Offshore System	Transco Energy Marketing Co	04-27-90	K-S	190,800,000
ST90-2734	High Island Offshore System	Sun Operating Limited Partnership	04-27-90	K-S	1,560,000
ST90-2735	Mississippi River Transmission Corp	Tex/Con Gas Pipeline Co	04-27-90	B	100,000
ST90-2736	Mississippi River Transmission Corp	Energy Marketing Exchange, Inc	04-27-90	G-S	102,500
ST90-2737	Mississippi River Transmission Corp	Laclede Steel Co	04-27-90	G-S	11,705
ST90-2738	Mississippi River Transmission Corp	Cerro Copper Products Co	04-27-90	G-S	1,306
ST90-2739	Mississippi River Transmission Corp	General Chemical Corp	04-27-90	G-S	116
ST90-2740	Mississippi River Transmission Corp	Spectrulite Cansortium, Inc	04-27-90	G-S	2,290
ST90-2741	Columbia Gulf Transmission Co	Coastal Gas Marketing Co	04-27-90	G-S	30,000
ST90-2742	Delhi Gas Pipeline Corp	Northern Natural Gas Co	04-30-90	C	2,000
ST90-2743	Stingray Pipeline Co	Louisiana Gas Marketing Co	04-30-90	B	50,000
ST90-2744	Stingray Pipeline Co	Enron Industrial Natural Gas Co	04-30-90	B	50,000
ST90-2745	Stingray Pipeline Co	Tennessee Gas Pipeline Co	04-20-90	K	10,000
ST90-2746	Northern Natural Gas Co	Iowa Electric Light & Power Co	04-30-90	B	20,000
ST90-2747	Northern Natural Gas Co	Adobe Gas Co	04-30-90	B	4,680
ST90-2748	Natural Gas Pipeline Co. of America	North Shore Gas Co	04-30-90	B	20,000
ST90-2749	Natural Gas Pipeline Co. of America	Dyco Gas Marketing	04-30-90	G-S	30,000
ST90-2750	Natural Gas Pipeline Co. of America	Mitchell Marketing Co	04-30-90	G-S	20,000
ST90-2751	Natural Gas Pipeline Co. of America	Tennessee Gas Pipeline Co	04-30-90	G	15,000
ST90-2752	Enserch Gas Transmission Co	Trunkline Gas Co	04-30-90	C	50,000
ST90-2753	Lone Star Gas Co	El Paso Natural Gas Co., et. al	04-30-90	C	100,000
ST90-2754	Valero Interstate Transmission Co	Valero Transmission , L.P	04-30-90	B	3,500
ST90-2755	Williston Basin Interstate P/L Co	Coastal States Gas Transmission Co	04-30-90	B	55,500
ST90-2756	Sonat Intrastate-Alabama Inc	Southern Natural Gas Co	04-30-90	C	85,000
ST90-2757	Columbia Gulf Transmission Co	Exxon Corp	04-30-90	G-S	22,000
ST90-2758	Transok, Inc	Wisconsin Power and Light Co	04-30-90	C	50,000
ST90-2759	Transok, Inc	Natural Gas Pipeline Co. of America	04-30-90	C	50,000
ST90-2760	Northern Border Pipeline Co	Northern Natural Gas Co	04-30-90	G	10,000
ST90-2761	Northern Border Pipeline Co	Northern Natural Gas Co	04-30-90	G	100,000
ST90-2762	Northern Border Pipeline Co	Coastal Gas Marketing Co	04-30-90	G-S	200,000
ST90-2763	Northern Border Pipeline Co	Michigan Gas Co	04-30-90	B	50,000
ST90-2764	Northern Border Pipeline Co	Coastal Gas Marketing Co	04-30-90	G-S	100,000
ST90-2765	Northern Border Pipeline Co	Northern Natural Gas Co	04-30-90	G	200,000
ST90-2766	Transcontinental Gas Pipe line Corp	Fort Hill Natural Gas Authority	04-30-90	B	5,952

Docket No. [1]	Transporter/seller	Recipient	Date filed	Part 284 subpart	Estimated maximum daily quantity [2]
ST90-2767	Transcontinental Gas Pipe line Corp	Frederick Gas Co	04-30-90	B	1,000
ST90-2768	Transcontinental Gas Pipe line Corp	Frederick Gas Co	04-30-90	B	2,222
ST90-2769	Transcontinental Gas Pipe line Corp	Eastern Shore Natural Gas Co	04-30-90	G	8,824
ST90-2770	Colorado Interstate Gas Co	Kansas Power and Light Co	04-30-90	B	2,500
ST90-2771	Colorado Interstate Gas Co	Enron Industrial Natural Gas Co	04-30-90	B	100,000
ST90-2772	Colorado Interstate Gas Co	North Central Oil Corp	04-30-90	G-S	25,000
ST90-2773	Colorado Interstate Gas Co	North Central Oil Corp	04-30-90	G-S	25,000
ST90-2774	Colorado Interstate Gas Co	Questar Energy Co	04-30-90	G-S	25,000
ST90-2775	Colorado Interstate Gas Co	Sun Gas Transmission L.P	04-30-90	G-S	30,000
ST90-2776	Colorado Interstate Gas Co	North Central Oil Corp	04-30-90	G-S	25,000
ST90-2777	Colorado Interstate Gas Co	North Central Oil Corp	04-30-90	G-S	25,000
ST90-2778	Colorado Interstate Gas Co	City of Springfield	04-30-90	B	8,000
ST90-2779	Colorado Interstate Gas Co	OXY U.S.A., Inc	04-30-90	G-S	17,000
ST90-2780	Mississippi River Transmission Corp	ASARCO, Inc	04-30-90	G-S	800
ST90-2781	Mississippi River Transmission Corp	Amgas, Inc	04-30-90	G-S	450
ST90-2782	Mississippi River Transmission Corp	Louisiana Intrastate Gas Co	04-30-90	B	40,000
ST90-2783	Mississippi River Transmission Corp	National Steel Corp	04-30-90	G-S	22,700
ST90-2784	Mississippi River Transmission Corp	PPG Industries, Inc	04-30-90	G-S	2,700
ST90-2785	Mississippi River Transmission Corp	Pfizer Pigments, Inc	04-30-90	G-S	950
ST90-2786	Mississippi River Transmission Corp	General Motors Corp	04-30-90	G-S	5,419
ST90-2787	Mississippi River Transmission Corp	The DOE Run Co	04-30-90	G-S	1,125
ST90-2788	Mississippi River Transmission Corp	Laroche Industries, Inc	04-30-90	G-S	815
ST90-2789	Mississippi River Transmission Corp	Chevron U.S.A., Inc	04-30-90	G-S	27,500
ST90-2790	Mississippi River Transmission Corp	GAF Chemical Corp	04-30-90	G-S	1,530
ST90-2791	Mississippi River Transmission Corp	Mississippi Line Co	04-30-90	G-S	4,000

[1] Notice of transactions does not constitute a determination that filings comply with commission regulations in accordance with Order No. 436 (final rule and Notice Requesting Supplemental Comments, 50 FR 42372, 10/10/85).
[2] Estimated maximum daily volumes includes volumes reported by the filing company in MMBTU, MCF and DT.

[FR Doc. 90-14196 Filed 6-19-90; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. RP90-22-000]

Algonquin Gas Transmission Co.; Informal Settlement Conference

June 8, 1990.

Take notice that an informal settlement conference will be convened in this proceeding on Wednesday, June 20, 1990, at 1:30 a.m., at the offices of the Federal Energy Regulatory Commission, 810 First Street NE., Washington, DC 20426, for the purpose of exploring the possible settlement of the above-referenced docket.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined by 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214).

For additional information, contact Marc G. Denkinger (202) 208-2215 or David R. Cain (202) 208-0917.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 90-14187 Filed 6-19-90; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. RP90-128-000]

Chandeleur Pipe Line Co.; Petition For Waiver

June 12, 1990.

Take notice that on May 31, 1990, Chandeleur Pipe Line Company (Chandeleur) filed with the Federal Energy Regulatory Commission a petition for waiver of § 2.65(b) of the Commission's regulations, 18 CFR 2.65(b) (1988).

Chandeleur requests that the Commission grant the petition for waiver requested so that representative billing determinants are based upon volumes currently being transported on the system. Chandeleur is requesting waiver at this time claiming it can no longer comply with the regulation's requirements because current circumstances restrict pipeline throughout. Chandeleur claims that those circumstances include the limited nature of Chandeleur's current pipeline operations, depleting reserves in the Main Pass Block 41 Field, Offshore Louisiana (which are the primary sources of the transported supplies); inability to explain its system at this time to connect additional supply and delivery points, and the lack of actual demand by producers and shippers for transportation capacity.

Chandeleur states that the waiver would allow Chandeleur to collect its actual operating costs and return thereon pending the Commission's decision in the *Mobile Bay* proceeding in Docket No. CP89-518-000.

Chandeleur states that absent a waiver, Chandeleur's Order No. 509 rate now pending consideration in Docket No. RP89-86-000 would result in a substantial undercollection of Chandeleur's cost of service, and would also impose a penalty upon Chandeleur as a result of factors outside of Chandeleur's control, independent of Chandeleur's ongoing efforts to solicit new transporters for its system.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before July 2, 1990. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 90-14195 Filed 6-19-90; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. RP90-70-000]

Equitrans, Inc.; Informal Settlement Conference

June 13, 1990.

Take notice that a conference will be convened in the above-captioned proceeding on June 28, 1990 at 10 a.m., at the offices of the Federal Energy Regulatory Commission, 810 First Street NE., Washington, DC 20426, for the purpose of exploring the possible settlement of the issues in this proceeding.

Any party, as defined by 18 CFR 385.102(c), or any participant as defined by 18 CFR 385.102(b), is invited to attend. Persons wishing to become a party must move to intervene and receive intervenor status pursuant to the Commission's regulations (18 CFR 385.214 (1989)).

For additional information, contact Arnold H. Meltz [(202) 208-0737] or Jennifer Corwin [(202) 208-0740].

Linwood A. Watson,

Acting Secretary.

[FR Doc. 90-14216 Filed 6-19-90; 8:45 am]

BILLING CODE 6717-01-M

[Project No. 2641 New York]

Niagara Mohawk Power Corp.; Intent To File Application for New License

June 13, 1990.

Take notice that Niagara Mohawk Power Corporation, the existing licensee for the Feeder Dam Transmission Line Project No. 2641, filed a timely notice of intent to file an application for a new license, pursuant to 18 CFR 16.6 of the Commissions Regulations (revised January 9, 1990). The original license for Project No. 2641 was issued effective April 1, 1949, and expires December 31, 1993.

The project is located in Saratoga County, New York. The principal works of the Feeder Dam Transmission Line Project consist of a substation with three step-up transformers at Feeder Dam Project No. 2554 (Moreau Manufacturing Corp. licensee) and a 34.5 kV transmission line extending from the substation to the Queensbury-Henry Street 34.5 kV line.

Pursuant to 18 CFR 16.7, the licensee is required henceforth to make available certain information to the public. This information is now available from the licensee 300 Erie Boulevard West, Syracuse, New York 13202, Building A-1, Attn: Barbara J. Raymond, C.R.M., Telephone No. (315) 428-6353.

Pursuant to 18 CFR 16.8, 16.9 and 16.10, each application for a new license and any competing license applications must be filed with the Commission at least 24 months prior to the expiration of the existing license. All applications for license for this project must be filed by December 31, 1991.

Lois D. Cashell,

Secretary.

[FR Doc. 90-14200 Filed 6-19-90; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TQ90-3-59-000]

Northern Natural Gas Co.; Division of Enron Corp.; Proposed Changes in Ferc Gas Tariff

June 13, 1990.

Take notice that Northern Natural Gas Company, Division of Enron Corp. (Northern), on June 1, 1990, tendered for filing changes in its FERC Gas Tariff, Third Revised Volume No. 1 (Volume No. 1 Tariff) and Original Volume No. 2 (Volume No. 2 Tariff).

Northern is filing the revised tariff sheets to adjust its Base Average Gas Purchase Cost in accordance with the Quarterly PGA filing requirements codified by the Commission's Order Nos. 483 and 483-A. The instant filing reflects a Base Average Gas Purchase Cost of $1.4756 per MMBtu to be effective July 1, 1990, through September 30, 1990. Northern further intends to use its flexible PGA, as necessary, to reflect actual market conditions throughout this time period.

Also the instant filing establishes, when necessary, new Demand rates in compliance with the above referenced PGA rulemaking. Such required Northern to adjust its PGA demand rate components on a quarterly versus annual basis. The PGA Demand D1 rate for the third quarter remains unchanged from the second quarter at $2.814 per MMB tu. This rate will be effective July 1, 1990 through September 30, 1990.

Copies of the filing were served upon the company's jurisdictional sales customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with §§ 385.214 and 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before June 20, 1990. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Linwood A. Watson, Jr.,

Acting Secretary.

[FR Doc. 90-14197 Filed 6-19-90; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. G-19806-004, et al.]

OXY USA Inc. (Successor-In Interest to OXY NGL Inc.); Application

June 13, 1990.

Take notice that on January 16, 1990, OXY USA Inc. of P.O. Box 300, Tulsa, Oklahoma 74102, filed an application pursuant to section 7 of the Natural Gas Act and parts 154 and 157 of the Federal Energy Regulatory Commission's (Commission) regulations thereunder for a certificate of public convenience and necessity to authorize it to render the service previously authorized by the Commission under certain certificates issued to OXY NGL Inc. and for substitution of OXY USA Inc. for OXY NGL Inc. in any other related proceedings. OXY USA Inc. also requests that the rate schedule of OXY NGL Inc. be redesignated as the rate schedules of OXY USA Inc. The application is on file with the Commission and is open for public inspection.

Effective January 1, 1990, OXY NGL Inc. was merged into OXY USA Inc. as evidenced by an Agreement and Articles of Merger dated December 15, 1989. The certificates and rate schedules proposed to be redesignated are listed in the appendix hereto.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 3, 1990, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party in any proceeding herein must file a petition to intervene in accordance with the Commission's rules.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for OXY USA Inc. to

appear or to be represented at the hearing.

Lois D. Cashell,

Secretary.

Appendix

OXY NGL Inc. FERC gas rate schedule No.	Certificate docket No.	Purchaser
1	G-19806	Transwestern Pipeline Co.
5	CI61-1332	Transwestern Pipeline Co.
6	CI65-561	Natural Gas Pipeline Company of America
7	G-18297	K N Energy, Inc.
12	CI84-4	Williston Basin Interstate Pipeline Co.

[FR Doc. 90-14194 Filed 6-19-90; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP72-121-021 et al.]

Paiute Pipeline Co. et al.; Filing of Pipeline Refund Reports

June 12, 1990.

Take notice that the pipelines listed below have submitted to the Commission for filing purposes refund reports.

Filing date	Company name	Docket No.
4/10/90	Paiute Pipeline Co	RP72-121-021
4/20/90	Williston Basin Interstate Pipeline Co.	CP82-487-028
4/26/90	Midwestern Gas Transmission Co.	RP89-35-011
5/1/90	Algonquin Gas Transmission Co.	RP87-14-009
5/10/90	Questar Pipeline Co	RP89-120-005
5/11/90	Willison Basin Interstate Pipeline Co.	CP82-487-029

Any person wishing to do so may submit comments in writing concerning the subject refund reports. All such comments should be filed with or mailed to the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, on or before July 3, 1990. Copies of the respective filings are on file with the Commission and available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 90-14201 Filed 6-19-90; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP89-925-001 and RP89-73-007]

Pelican Interstate Gas System; Compliance Tariff Filing

June 13, 1990.

Take notice that on June 8, 1990, in compliance with the Order Approving Abandonment in Docket No. CP89-925-000 and the Order Modifying and Approving Uncontested Settlement in Docket No. RP89-73-000 Pelican Interstate Gas System (Pelican) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 1 the following tariff sheets.

Docket No. CP89-925-000

First Revised Sheet No. 6
Second Revised Sheet No. 17
First Revised Sheet No. 18

Docket No. RP89-73-000

First Revised Sheet No. 2B
Original Sheet No. 17A
Original Sheet No. 17B
Original Sheet No. 17C
Second Revised Sheet No. 18
First Revised Sheet No. 42
Original Sheet No. 42A
First Revised Sheet No. 45
Original Sheet No. 45A
First Revised Sheet No. 57
Original Sheet No. 57A
First Revised Sheet No. 91
First Revised Sheet No. 95

Pelican states that copies of this filing have been served upon Pelican's tariff holders, interested parties and interested state commissions.

Any person desiring to be heard or to protest said filings should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests must be filed on or before June 20, 1990. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 90-14198 Filed 6-19-90; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP90-105-001]

Transwestern Pipeline Co.; Compliance Filing

June 13, 1990.

Take notice that Transwestern Pipeline Company (Transwestern) on June 8, 1990 tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, the following tariff sheets:

Effective June 1, 1990

Substitute 1st Revised Sheet No. 81A
Substitute Original Revised Sheet No. 81B

Statement of Purpose, Reason and Nature of Filing

On April 27, 1990, Transwestern filed tariff sheets to: (1) revise Rate Schedules FTS-1 and ITS-1 to permit Transwestern, on a not unduly discriminatory basis, to install or modify facilities that are necessary to provide transportation services without receiving reimbursement; and (2) refine the procedures for an ITS-1 Shipper to elect to pay the Maximum ITS-1 Transport Charge during the month.

By order dated May 31, 1990, the Commission accepted the tariff sheets filed April 27, 1990 to be effective June 1, 1990, subject to certain conditions. The May 31, 1990 Order directed Transwestern to revise tariff language to clarify that discounted shippers and challenging shippers will be obligated to pay the maximum ITS-1 rate only for as long as the challenging shippers nominate to use the service.

Ordering Paragraph (B) of the May 31, 1990 Order required Transwestern to file revised tariff sheets. Pursuant to and in compliance with the May 31, 1990 Order, Transwestern submitted the above referenced tariff sheets.

Transwestern respectfully requests that the Commission grant any and all waivers of its rules, regulations and orders as may be necessary so as to permit the above listed tariff sheets to become effective June 1, 1990, as provided in the May 31, 1990 Order.

Transwestern states that copies of the filing were served on Transwestern's jurisdictional customers and interested state commissions.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC, 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed on or before June 20, 1990. Protests will be considered by the Commission in

determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 90-14199 Filed 6-19-90; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[OPP-30306; FRL-3765-7]

Pentachloronitrobenzene; Receipt of Request to Amend Registrations to Delete Potato Use

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of receipt.

SUMMARY: This notice, pursuant to section 6(f)(1) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. 136 et seq., announces EPA's receipt of a request from the Uniroyal Chemical Company, Inc. to amend the registration of their pentachloronitrobenzene (PCNB) pesticide products to delete all potato uses. The products are marketed under the tradenames Terraclor® 75 WP (EPA Registration No. 400-399), Terraclor® 2lb EC (EPA Registration No. 400-400) and Terraclor® 10G (EPA Registration No. 400-402). EPA expects to approve these requests thereby amending affected registrations of Uniroyal products containing PCNB.

DATES: The modifications of registrations shall be effective July 20, 1990, and all future distribution, sale, or use of affected PCNB products shall be in accordance with the terms and conditions described herein.

FOR FURTHER INFORMATION CONTACT: Susan T. Lewis, Product Manager (PM) 21, Registration Division (H7505C), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460. Office location and telephone number: Rm. 227, CM #2, 1921 Jefferson Davis Highway, Arlington, VA, 703-557-1900.

SUPPLEMENTARY INFORMATION: On April 18, 1990, Uniroyal Chemical Company, Inc., 74 Amity Road, Bethany, CT 06525 submitted applications to amend the registration of Terraclor® 75 WP (EPA Registration No. 400-399), Terraclor® 2lb EC (EPA Registration No. 400-400) and Terraclor® 10G (EPA Registration No. 400-402) to delete the potato use. Uniroyal intends to neither recommend nor market Terraclor® for use on potatoes until a permanent tolerance is established for residues of PCNB in the future. Currently, an interim tolerance is established under 40 CFR 180.319 for PCNB in or on potatoes at 0.1 parts per million. Recently conducted residue data indicate that due to unknown factors the use of PCNB on potatoes following label directions in some cases may result in residues that exceed the interim tolerance. Under the Federal, Food, Drug, and Cosmetic Act, 21 U.S.C. 334, 342, and 346a, raw agricultural commodities with pesticide residues that exceed established tolerances are considered adulterated and are subject to seizure and destruction.

EPA has reviewed the existing stocks and relabeling elements of the registrant's request and has concluded that all existing stocks under the control of Uniroyal must be relabeled within 1 month of EPA's approval of the request for use deletion, and all new products as produced must bear approved labels reflecting the use restriction.

EPA has received and expects to approve the request described above effective July 20, 1990, incorporating the requested actions and the existing stocks provisions as described above.

Dated: May 31, 1990.

Stephanie R. Irene,

Acting Director, Registration Division.

[FR Doc. 90-13931 Filed 6-19-90; 8:45 am]

BILLING CODE 6560-50-D

[OPTS-53127A; FRL 3769-3]

Premanufacture Notices; Monthly Status Report for January 1990; Correction

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice correction.

SUMMARY: EPA is correcting the Monthly Status Report for January 1990 which was inadvertently published with the heading "Monthly Status Report for January 1989".

ADDRESSES: Written comments, identified by the document control number [OPTS-53127A] and the specific PMN number should be sent to: Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, 401 M Street, SW., Room L-100, Washington DC 20460 (202) 382-3532.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Division (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room EB-44, 401 M Street, SW., Washington, DC 20460 (202) 382-3725.

SUPPLEMENTARY INFORMATION: In FR Doc. 90-8029, appearing in the **Federal Register** of April 9, 1990 (55 FR 13189), wherever the Monthly Status Report for January 1989 appears, change it to read January 1990.

Dated: June 14, 1990.

Douglas W. Sellers,

Acting Director, Information Management Division, Office of Toxic Substances.

[FR Doc. 90-14261, Filed 6-19-90; 8:45 am]

BILLING CODE 6560-50-D

[OPTS-59284; FRL 3771-2]

Toxic and Hazardous Substances; Certain Chemicals Premanufacture Notices; Test Market Exemption Applications

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA may upon application exempt any person from the premanufacturing notification requirements of section 5(a) or (b) of the Toxic Substance Control Act (TSCA) to permit the person to manufacture or process a chemical for test marketing purposes under section 5(h)(1) of TSCA. Requirements for test marketing exemption (TME) applications, which must either be approved or denied within 45 days of receipt are discussed in EPA's final rule published in the **Federal Register** of May 13, 1983 (48 FR 21722). This notice, issued under section 5(h)(6) of TSCA, announces receipt of three application(s) for exemption, provides a summary, and requests comments on the appropriateness of granting this exemption.

DATES:

Written comments by:

T 90-12, June 14, 1990.
T 90-13, June 23, 1990.
T 90-14, June 30, 1990.

ADDRESSES: Written comments, identified by the document control number "(OPTS-59284)" and the specific TME number should be sent to: Document Processing Center (TS-790), Office of Toxic Substances, Environmental Protection Agency, 401 M Street, SW., Room L-100, Washington, DC 20460, (202) 382-3532.

FOR FURTHER INFORMATION CONTACT: Michael M. Stahl, Director, Environmental Assistance Office (TS-799), Office of Toxic Substances, Environmental Protection Agency, Room

E–545, 401 M Street, SW., Washington, DC 20460, (202) 554–1404, TDD (202) 554–0551.

SUPPLEMENTARY INFORMATION: The following notice contains information extracted from the nonconfidential version of the submission provided by the manufacturer of the TME received by EPA. The complete nonconfidential document is available in the Public Reading Room NE–G004 at the above address between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding legal holidays.

T 90–12

Close of Review Period. June 28, 1990.

Manufacturer. Confidential.

Chemical. (G) Ligninkraft, reaction product with tall oil fatty acids, C21 dicarboxylic acid and ethylene amines.

Use/Production. (G) Emulsifer for asphalt emulsions. Prod. range: Confidential.

T 90–13

Close of Review Period. July 7, 1990.

Importer. Confidential.

Chemical. (G) 88% polyvinyl alcohol with residual acetate group; 3,4-dimethyl-2-(2-(4-formalphenyl)thiazolium methanesulphate.

Use/Import. (G) Screen printing chemical. Import range: Confidential.

Toxicity Data. Acute orial toxicity: LD50 < 5.0 g/kg species (Rat). Acute dermal toxicity: LD50 < 2.0 g/kg species (Rabbit). Eye irritation: slight species (Rabbit). Skin irritation: negligible species (Rabbit). Mutagenicity: negative. Skin sensitization: negative species (Guinea Pig).

T 90–14

Close of Review Period. July 14, 1990.

Manufacturer. Confidential.

Chemical. (S) Aqueous polyurethane dispersion group; 3,4-dimethyl-2-(2-(4-formalphenyl)thiazolium methanesulphate.

Use/Production. (S) As a finish for leather a bonding or finishing for treatment for textiles. Prod. range: 19,000–115,000 kg/yr.

Dated: June 14, 1990.

Douglas Sellers,

Acting Director, Information Management Division, Office of Toxic Substances.

[FR Doc. 90–14262 Filed 6–19–90; 8:45 am]

BILLING CODE 6560–50–D

[FRL–3789–3]

Extension of the Period for Action on a Recommended Section 404(c) Determination to Prohibit the Specification or Use of an Area as a Disposal Site: South Platte River

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of an extension to the period for action on a recommended section 404(c) determination.

SUMMARY: On April 17, 1990, EPA Headquarters received Regional documentation including an administrative record supporting a recommended determination to prohibit specification of an area of the South Platte River in Douglas and Jefferson Counties, Colorado. The subject site is proposed as a disposal site for fill material necessary for the construction of a water supply impoundment known as the Two Forks reservoir. In accordance with EPA's section 404(c) regulations, EPA Headquarters has initiated final consultation with the Crops of Engineers, the owners of record and the section 404 permit applicants for the proposed project. The section 404 permit applicants, the Denver Water Board and the Metropolitan Water Providers, have requested that consultation not begin until August, 1990. EPA has agreed to the extension.

In addition, EPA has determined that the substantial volume of material contained in the administrative record requires additional time for review prior to rendering a final decision with regard to the Two Forks proposal. EPA, therefore, has determined that good cause exists to extend the time limit for preparation of a final determination on the recommended determination to prohibit specification of the subject area. EPA's deadline for a Final Determination is being extended until close of business, December 14, 1990. This time extension is made under the EPA authority found in 40 CFR 231.8.

FOR FURTHER INFORMATION CONTACT: William S. Garvey, Elevated Cases Team (A–104–F), Office of Wetlands Protection—U.S. EPA, 401 M Street, Washington, D.C. 20460, (202) 475–7799.

Dated: June 13, 1990.

LaJuana S. Wilcher,

Assistant Administrator for Water.

[FR Doc. 90–14267 FILED 6–29–90; 8:45 am]

BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

June 14, 1990.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, International Transcription Service, (202) 857–3800, 2100 M Street NW., suite 140, Washington, DC 20037. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 632–7513. Persons wishing to comment on this information collection should contact Eyvette Flynn, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503, (202) 395–3785.

OMB Number: 3060–0233.

Title: Part 36, Jurisdictional Separations Procedures.

Action: Extension.

Respondents: Businesses or other for-profit.

Frequency of Response: Annually and a one-time filing requirement (§ 36.721).

Estimated Annual Burden: 3,090 Responses; 61,800 Hours.

Needs and Uses: Telephone companies are required to submit data annually to the National Exchange Carrier Association (NECA) for the filing of access tariffs. State or local telephone companies who want to participate in the federal assistance program must make certain informational showings to demonstrate eligibility. The information collections as defined by 5 CFR 1320 are contained in three sections of part 36–36.611, 36.721, and 36.731. Information filed with NECA pursuant to § 36.611 is used in the jurisdictional allocations underlying the cost support data for the access charge tariffs every October. Without this information, NECA would not be able to prepare and file the necessary tariffs. Information submitted to the Commission pursuant to § 36.721 is required to maintain integrity of the Federal Lifeline Assistance Programs. Certification is necessary to ensure that the target group is the beneficiary of the program.

Federal Communications Commission.
Donna R. Searcy,
Secretary.
[FR Doc. 90-14279 Filed 6-19-90; 8:45 am]
BILLING CODE 6712-01-M

FEDERAL RESERVE SYSTEM

Creditanstalt-Bankverein Vienna, Austria; Application To Provide Brokerage Services on Separate Basis, Investment Advisory and Brokerage Services on Combined Basis, To Buy and Sell Securities on Order of Investors As "Riskless Principal," and To Provide Certain Corporate Financial Advisory Services

Creditanstalt-Bankverein, Vienna, Austria ("Creditanstalt"), has applied pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) (the "BHC Act") and § 225.23(a) of the Board's Regulation Y (12 CFR 225.23(a)), for prior approval to engage through its wholly-owned subsidiary, Creditanstalt International Advisers, Inc., New York, New York ("Advisers"), in providing investment advisory and securities brokerage services on a combined basis ("full service securities brokerage"), providing brokerage services separately, and acting as "riskless principal." Creditanstalt also proposes to engage, through Advisers, in the following corporate financial advisory activities:

(a) Furnishing general economic information and advice, general economic statistical forecasting services and industry studies;

(b) Providing financial advice to state and local governments, such as with respect to the issuance of their securities;

(c) Providing advice regarding the structuring of and arranging for loan syndications, interest rate "swaps," interest rate "caps," and similar transactions;

(d) Providing advice in connection with financing transactions;

(e) Providing valuation services;

(f) Providing advice in connection with mergers, acquisitions and divestitures;

(g) Rendering fairness opinions in connection with mergers, acquisitions, and similar transactions; and

(h) Conducting feasibility studies.

Company would conduct the proposed activities on a domestic and international basis.

Creditanstalt acquired all of Advisers' shares indirectly on December 29, 1989. Pursuant to section 4(c)(9) of the BHC Act and § 211.23(f)(3) of Regulation K, Creditanstalt currently engages through Advisers in brokerage and investment advisory services, including mergers and acquisition advice, that are "incidental" to its foreign or international business. Creditanstalt seeks authority under section 4(c)(8) of the BHC Act, so that it may provide these services generally to its U.S. customers.

Section 4(c)(8) of the BHC Act provides that a bank holding company may, with prior Board approval, engage directly or indirectly in any activities "which the Board after due notice and opportunity for hearing has determined (by order or regulation) to be so closely related to banking or managing or controlling banks as to be proper incident thereto."

The Board has previously determined that engaging in full service brokerage activities is closely related and a proper incident to banking. *See. e.g., National Westminster Bank PLC,* 72 Federal Reserve Bulletin 584 (1986) ("*Natwest*"). Creditanstalt has committed to conduct these activities subject to the limitations in *Natwest,* as they were modified in *The Toronto Dominion Bank,* 76 Federal Reserve Bulletin _____ (1990), *Bankers Trust New York Corporation,* 74 Federal Reserve Bulletin 695 (1988) ("*Bankers Trust*"), *Canadian Imperial Bank of Commerce,* 74 Federal Reserve Bulletin 571 (1988), *The Bank of Nova Scotia,* 74 Federal Reserve Bulletin 249 (1988), and *Manufacturers Hanover Corporation,* 73 Federal Reserve Bulletin 930 (1987). Creditanstalt also proposes that one officer of its New York branch be permitted to serve as a director of Advisers. The Board has previously permitted a similar interlock. *See. The Bank of Tokyo, Ltd.,* 76 Federal Reserve Bulletin _____ (1990).

Creditanstalt also seeks authority for Advisers, without defined parameters establihed by institutional customers, to exercise discretion in buying and selling securities on behalf of institutional customers. This service would be performed solely for institutional customers subject to the conditions in *J.P. Morgan & Co. Incorporated,* 73 Federal Reserve Bulletin 810, 811 (1987).

In addition, Creditanstalt proposes to conduct riskless principal activities. The Board has approved the purchase and sale of all types of securities on the order of investors as "riskless principal" under certain limitations. *See, e.g., Stichting Amro and Amsterdam-Rotterdam Bank N.V.,* 76 Federal Reserve Bulletin 29 (1990); *Bankers Trust New York Corporation,* 75 Federal Reserve Bulletin 829 (1989). Creditanstalt has proposed to conduct this activity within the limitations placed on these activities in previous Board decisions.

Creditanstalt also proposes to offer brokerage services separately from the provision of investment advice, pursuant to § 225.25(b)(15) of Regulation Y (12 CFR 225.25(b)(15)).

The Board has previously determined that the proposed corporate advisory services are closely related and a proper incident of banking. The activities described in paragraphs (a) and (b) are permissible nonbanking activities pursuant to subsections 225.25(b)(4) (iv) and (v) of Regulation Y (12 CFR 225.25(b)(4) (iv) and (v)). The Board has determined by Order that the remaining proposed financial advisory services are closely related and a proper incident to banking. *See, e.g., Signet Banking Corporation,* 73 Federal Reserve Bulletin 744 (1987); *Scandinavian Bank Group plc,* 75 Federal Reserve Bulletin 572 (1989). Advisors will conduct these activities in conformance with the limitations of Regulation Y and these Orders.

In determining whether an activity is a proper incident to banking, the Board must consider whether the proposal may "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interest, or unsould banking practices." 23 U.S.C. 1843(c)(8). Creditanstalt contends that permitting it to engage in the proposed activities would result in increased competition, greater convenience to customers, and increased efficiency in the provision of financial services. Moreover, Creditanstalt believes that the proposed activities will not result in any unsound banking practices or other adverse effects.

In publishing the proposal for comment the Board does not take a position on issues raised by the proposal. Notice of the proposal is published solely in order to seek the views of interested persons on the issues presented by the application and does not represent a determination by the Board that the proposal meets or is likely to meet the standards of the BHC Act or the Glass-Steagall Act.

Any comments or requests for a hearing should be submitted in writing and received by William W. Wiles, Secretary, Board of Governors of the Federal Reserve System, Washington, DC 20551, not later than July 17, 1990. Any request for a hearing on this application must, as required by section 262.3(e) of the Board's Rules of Procedure (12 CFR 262.3(e)), be accomplished by a statement of reasons

why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

This application may be inspected at the offices of the Board of Governors of the Federal Reserve Bank of New York.

Board of Governors of the Federal Reserve System, June 14, 1990.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 90-14217 Filed 6-19-90; 8:45 am]

BILLING CODE 6210-01-M

United Missouri Bancshares, Inc.; Formation of, Acquisition by, or Merger of Bank Holding Companies

The company listed in this notice has applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.24) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that application or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Comments regarding this application must be received not later than July 10, 1990.

A. Federal Reserve Bank of Kansas City (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *United Missouri Bancshares, Inc.*, Kansas City, Missouri; to acquire 100 percent of the voting shares of Liberty National Bank, Liberty, Missouri.

Board of Governors of the Federal Reserve System, June 14, 1990.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 90-14218 Filed 6-19-90; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

[Announcement Number 027]

Sentinel Evaluation Projects for the Prevention of Sexual and Perinatal Transmission of Human Immunodeficiency Virus (HIV) Within the Hemophilia Community; Program Announcement and Notice of Availability of Fiscal Year 1990 Funds

Introduction

The Centers for Disease Control (CDC) announces that cooperative agreement applications are to be accepted for Fiscal Year 1990 for evaluation projects to prevent sexual and perinatal transmission of human immunodeficiency virus (HIV) in persons with hemophilia.

Authority: This program is authorized under the Public Health Service Act, Section 301(a) [42 U.S.C. 241(a)], as amended, and section 317 (42 U.S.C. 247b), as amended.

Eligibility

Because of the low prevalence of hemophilia, the multi-center nature of the proposed research, and the stated purpose of targeting individuals in hemophilia treatment centers, eligible applicants for these projects are the public, nonprofit private, and state and local government hemophilia treatment centers and other hemophilia programs located in the States, the District of Columbia, and the Commonwealth of Puerto Rico. These applicants are encouraged to involve universities or academic institutions to strengthen the project, particularly in the areas of behavioral science, health education, and/or data and evaluation. To ensure a valid sample, it is anticipated that approved applicants selected for funding for adult projects will have available a minimum of 25 adults and that approved applicants selected for funding for adolescent projects will have a minimum of 15 adolescents with hemophilia infected with HIV or considered at risk for HIV infection who are likely to participate in this study. Eligible treatment centers are encouraged to submit joint applications with other centers in close proximity to increase the size of their target population. Applicants who serve only adults are encouraged to submit joint applications with nearby applicants who serve only adolescents (and vice versa); however, this is not mandatory.

Availability of Funds

Approximately $1,200,000 is available in Fisal Year 1990 to fund up to 10 adult projects. It is expected that the average award will be $120,000, ranging from $100,000 to $200,000. Approximately $1,300,000 is available in Fiscal Year 1990 to fund up to 15 adolescent projects. It is expected that the average award will be $85,000, ranging from $80,000 to $130,000.

It is expected that cooperative agreements will being in September 1990, and will be funded for 12 months in a 3-year project period. Funding estimates outlined above may vary and are subject to change. Continuation awards witin the project period will be made on the basis of satisfactory progress and the availability of funds.

Purpose

The purpose of this project is to assist hemophilia programs in demonstrating the effectiveness of selected risk reduction interventions or methods for preventing new cases of HIV infection in sexual partners and/or preventing perinatal HIV primarily by preventing unintended pregnancy in sexual partners of HIV-infected men with hemophilia. Projects targeted to adolescents and adults will be supported. To draw statistically significant conclusions about the success of these interventions, recipients will be required to collaborate with each other in developing and implementing a common protocol.

There is an urgent need to identify and develop effective programs to prevent further HIV transmission within the hemophilia community. Successful programs will require strong collaborative efforts between the public and private sectors, and will need to provide appropriate risk reduction, education, and psychosocial support to persons with hemophilia and their sexual partners. Effective programs will need to address two distinct population groups: (1) Those persons with hemophilia actively served by a hemophilia treatment center; and (2) those persons with hemophilia not actively served by a center. Included in each group are two distinct populations: adults and their sexual partners; and adolescents, their sexual partners, and their parents. Because of their unique needs, these two populations need to be addressed separately. Funding priority

for the first year of this multi-year project will focus on adult and adolescents, actively served by hemophilia treatment centers.

Program Requirements

In conducting activities to achieve the purpose of this program, the recipient shall be responsible for conducting activities under A. below, and CDC will be responsible for conducting the activities under B. below.

A. Recipient Activities

1. Meet with CDC and other funded applicants to identify the optimal features of the proposed approaches and to incorporate them, when possible, into common protocols resulting in (a) Theoretically based approaches to intervention; and (b) an evaluation plan which will measure changes in knowledge, attitudes, intentions, and reproductive, sexual, and health care behaviors, plus changes in HIV seroincidence and unintended pregnancy rates among sexual partners. These common protocols would be used in all funded sites.
2. Meet with CDC to develop plans to integrate these new activities into recipient's existing programs.
3. Implement the protocol and evaluation plan as designed, integrating them into existing programs.
4. Prepare and share with CDC pertinent information on progress and findings in the form of quarterly reports.
5. Participate in the transfer of findings to other programs.

B. CDC Activities

1. Coordinate design of the protocol to be used in all demonstration sites.
2. Provide consultation and technical assistance in planning, operating, and evaluating activities for preventing HIV infection and AIDS.
3. Provide current scientific information regarding national program strategies for such prevention.
4. Provide assistance in data management and analysis.
5. Participate in the aggregate analysis of data gathered from program activities and the reporting of results.
6. Assist in the transfer of information and methods developed in these projects to other hemophilia programs, States, and communities.

Review and Evaluation Criteria

Competing applications addressing adult populations will be evaluated separately from those addressing adolescent populations. Priority may be given to applications containing both adult and adolescent components. All applications will be reviewed and evaluated according to the same criteria, as follows:

A. The extent of the applicant's commitment and ability to provide HIV prevention services, as evidenced by the quality and scope of the applicant's past and current activities to provide education, counseling, and outreach for HIV prevention and AIDS to high-risk individuals in the hemophilia community; and their demonstrated efforts to evaluate those activities (30 points);

B. The extent to which the applicant demonstrates an understanding of specific, measurable, time-phased objectives which are consistent with the stated purpose of this program and the extent to which behavioral and health impact and outcome objectives are included (10 points);

C. The extent to which the applicant demonstrates innovativeness, adaptability, and appropriateness in the development of potential interventions and strategies to: (1) Identify at-risk persons with hemophilia, their sexual partners, and appropriate family members, (2) motivate those individuals to make appropriate risk reduction behavior changes, and (3) reinforce those individuals once such behavior changes have occurred (25 points);

D. The extent to which the applicant demonstrates the ability to determine, monitor, and measure changes in HIV seroincidence and unintended pregnancy rates among sexual partners; and changes in specific knowledge, attitudes, beliefs, and self-reported behaviors among adults with hemophilia and their sexual partners, and among adolescents with hemophilia and their parents (15 points);

E. The extent to which the applicant identifies staff, training, equipment, and facilities needed to implement an intervention project (10 points);

F. The nature and extent of collaboration with universities or academic institutions, other hemophilia treatment centers or chapters, family planning agencies, and other relevant community groups; and the applicant's ability to generate support, cooperation, and collaboration from community-based organizations serving individuals at high risk of HIV infection (5 points);

G. The nature and extent of coordination with local and State health department HIV prevention programs (5 points).

Applications also will be reviewed according to the extent to which the budget request is clearly explained, adequately justified, reasonable, consistent with the intended use of cooperative agreement funds and the extent to which the applicant is contributing its own resources to HIV/AIDS prevention activities.

Funding Priorities

In funding approved applications, consideration will be given to the aggregate size of the target population and the nature and extent of existing research involving the targeted community.

Other Requirements

Recipients must comply with the document titled: Content of AIDS-Related Written Materials, Pictorials, Audiovisuals, Questionnaires, Survey Instruments, and Educational Sessions (October 1988). (54 FR 10049, March 9, 1989) In complying with the Program Review Panel requirements contained in the above document, recipients are encouraged to use an existing Program Review Panel such as the one created by the health department's HIV/AIDS Prevention Program.

Projects funded through a cooperative agreement that involve collection of information from 10 or more individuals will be subject to review under the Paperwork Reduction Act.

Executive Order 12372 Review

Applications are not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

Catalog of Federal Domestic Assistance Number

The Catalog of Federal Domestic Assistance Number is 13.118, Acquired Immunodeficiency Syndrome (AIDS) Activity.

Application Submission and Deadline

The original and two copies of the application (PHS form 5161–1) must be submitted to Edwin L. Dixon, Grants Management Officer, Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road NE., room 300, Mailstop E14, Atlanta, GA 30305, on or before August 1, 1990.

A. Deadline; Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date, or
2. Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants must request a legibly dated U.S. Postal Service postmark or obtain a legibly dated receipt from a commercial carrier or the U.S. Postal Service. Private

metered postmarks shall not be acceptable as proof of timely mailing.)

B. Late Applications

Applications which do not meet the criteria in A.1. or 2., above, are considered late applications. Late applications will not be considered in the current competition and will be returned to the applicant.

Where To Obtain Additional Information

A complete program description, information on application procedures and an application package may be obtained from Grants Management Branch, Clara Jenkins, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road NE., room 300, Altanta, GA 30305, or by calling (404) 842-6640 or FTS 236-6640.

Announcement Number 027, "Sentinel Evaluation Projects for the Prevention of Sexual and Perinatal Transmission of Human Immunodeficiency Virus (HIV) Within the Hemophilia Community" must be referenced in all requests for information pertaining to these projects.

Technical information may be obtained from Susan Schulz or Kevin O'Reilly, Division of Sexually Transmitted Diseases, Center for Prevention Services, Centers for Disease Control, (404) 639-0848, or FTS 236-0848; or Karen Meredith, Division of Immunologic, Oncologic and Hematologic Diseases (DIOHD), Center for Infectious Diseases, Centers for Disease Control, (404) 639-3750, or FTS 236-3750.

Dated: June 14, 1990.

Ladene H. Newton,

Acting Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 90-14248 Filed 6-19-90; 8:45 am]

BILLING CODE 4160-18-M

Health Care Financing Administration

Hearing; Reconsideration of Disapproval of Illinois Medicaid State Plan Amendment (SPA)

AGENCY: Health Care Financing Administration (HCFA), HHS.

ACTION: Notice of Hearing.

SUMMARY: This notice announces an administrative hearing on August 8, 1990, in the 16th floor conference room, 105 West Adams, Chicago, Illinois to reconsider our decision to disapprove Illinois State Plan Amendment 89-13.

CLOSING DATE: Requests to participate in the hearing as a party must be received by the Docket Clerk July 5, 1990.

FOR FURTHER INFORMATION CONTACT: Docket Clerk, HCFA Hearing Staff, 300 East High Rise, 6325 Security Boulevard, Baltimore, Maryland 21207, Telephone: (301) 966-4471.

SUPPLEMENTARY INFORMATION: This notice announces an administrative hearing to reconsider our decision to partially disapprove Illinois State Plan amendment (SPA) number 89-13.

Section 1116 of the Social Security Act (the Act) and 42 CFR part 430 establish Department procedures that provide an administrative hearing for reconsideration of a disapproval of a State plan or plan amendment. HCFA is required to publish a copy of the notice to a State Medicaid Agency that informs the agency of the time and place of the hearing and the issues to be considered. (If we subsequently notify the agency of additional issues that will be considered at the hearing, we will also publish that notice.)

Any individual or group that wants to participate in the hearing as a party must petition the Hearing Officer within 15 days after publication of this notice, in accordance with the requirements contained at 42 CFR 430.76(b)(2). Any interested person or organization that wants to participate as amicus curiae must petition the Hearing Office before the hearing begins in accordance with the requirements contained at 42 CFR 430.76(c).

If the hearing is later rescheduled, the Hearing Officer will notify all participants.

Illinois SPA 89-13 makes changes in the hospital peer group methodology, rate calculations, and in calculating disproportionate share hospital (DSH) payment adjustments for inpatient hospital services. Certain hospitals will be eligible for DSH payment adjustments, in addition to the federally-mandated DSHs, on the basis of variables such as location in a Health Manpower Shortage Area and the extent to which they provide services to children. The State requested that the amendment be effective July 1, 1989.

Federal regulations at 42 CFR 430.12(c) require a State plan to be amended to reflect new or revised Federal statutes or regulations or material changes in any phase of State law, organization, policy, or State agency operation. In accordance with Federal regulations at 42 CFR 447.253(f), the Medicaid agency must also comply with the public notice requirements in § 447.205 when it is proposing significant changes to its methods or standards for setting payment rates for inpatient hospital or long-term care facility services. Section 447.205(d)(1) requires that the notice be published before the proposed effective date of the change. Section 447.205 (c) and (d) set forth additional requirements regarding the content and publication of the notice.

The issue in this matter is whether the State published a public notice before the proposed July 1, 1990, effective date which meets the requirements of 42 CFR 447.253(f) and 42 CFR 447.205.

The plan amendment was submitted by the State on September 29, 1989, together with assurances and related rate information. The State published a public notice which met the requirements of 42 CFR 447.205 on April 1, 1988, for the State plan revisions regarding hospital groupings and rate calculations, and on September 1, 1989, for the changes regarding DSH payment adjustments. Accordingly, HCFA has determined that the effective date for this amendment cannot be July 1, 1989. However, HCFA approved the amendment with an effective date of July 1, 1989, for the revisions regarding the hospital groupings and rate calculations and September 2, 1989, with regard to the changes regarding DSH payment adjustments, the day following the publication of the State's notice.

The notice to Illinois announcing an administrative hearing to reconsider the partial disapproval of its State plan amendment reads as follows:

Ms. Kathleen Kustra,
Director, Illinois Department of Public Aid, Jesse B. Harris Building, 100 S. Grand Avenue East, Springfield, Illinois 62762-0001

Dear Ms. Kustra: I am responding to your request for reconsideration of the decision to partially disapprove Illinois State Plan Amendment (SPA) 89-13. The plan amendment makes changes in the hospital peer group methodology, rate calculations, and in calculating disproportionate share hospital (DSH) payment adjustments for inpatient hospital services with a proposed effective date of July 1, 1989. Certain hospitals will be eligible for DSH payment adjustments, in addition to the federally-mandated DSHs, on the basis of variables such as location in a Health Manpower Shortage Area and the extent to which they provide services to children.

The issue in this matter is whether the State published a public notice before the proposed July 1, 1990, effective date which meets the requirements of 42 CFR 447.253(f) and 42 CFR 447.205.

I am scheduling a hearing on your request to be held on August 8, 1990, at 10 a.m. in the 16th floor conference room, 105 West Adams, Chicago, Illinois. If this date is not acceptable, we would be glad to set another date that is mutually agreeable to the parties. The hearing will be governed by the procedures prescribed at 42 CFR Part 430.

I am designating Mr. Stanley Krostar as the presiding officer. If these arrangements

present any problems, please contact the Docket Clerk. In order to facilitate any communication which may be necessary between the parties to the hearing, please notify the Docket Clerk of the names of the individuals who will represent the State at the hearing. The Docket Clerk can be reached at (301) 966–4471.

Sincerely,

Gail R. Wilensky, Ph.D.,

Administrator.

(Section 1116 of the Social Security Act (42 U.S.C. 1316); 42 CFR 4301.18)

(Catalog of Federal Domestic Assistance Program No. 13.714, Medicaid Assistance Program)

Dated: June 13, 1990.

Gail R. Wilensky,

Administrator, Health Care Financing Administration.

[FR Doc. 90–14253 Filed 6–19–90; 8:45 am]

BILLING CODE 4120–03–M

Health Resources and Services Administration

Program Announcement for Nurse Anesthetist Faculty Fellowship Grants

The Health Resources and Services Administration (HRSA) announces that applications for Fiscal Year 1990 Nurse Anesthetist Faculty Fellowship Grants will be accepted under the authority of section 831(b) of the Public Health Service Act, and invites comments on the proposed criteria for fellows, policy on payment of stipends, funding preferences, and review criteria set out below.

Approximately $226,000 is available in Fiscal Year 1990 for competing awards. It is anticipated that approximately 30 awards will be made at an average of $7,533 each.

Purpose

Section 831(b) of the Public Health Service Act includes authority for grants for the purpose of providing financial assistance and support (fellowships) to certified registered nurse anesthetists (CRNA) who are faculty members of accredited programs to enable such nurse anesthetists to obtain advanced education relevant to their teaching functions.

Applicants

Public or private nonprofit institutions for the education of nurse anesthetists, which are accredited by an entity or entities designated by the Secretary of Education, may apply for grants to cover the cost of tuition and fees and certain stipends for currently employed CRNA faculty who qualify for a fellowship.

Proposed Criteria for Fellows

It is proposed that potential fellows must:

1. Be a CRNA employed by the applicant institution as a faculty member during the period of the awarded fellowship. Because the applicant institution may not be the educational institution in which the CRNA faculty member is enrolled, employment by the applicant institution provides the potential grantee reasonable controls in administering and monitoring the fellowship(s) and progress of the fellow(s). It also allows the potential grantee the freedom and authority to negotiate with the faculty member such areas as release time for full- or part-time study.

2. Be enrolled or accepted for enrollment in a master's degree program or in a doctoral degree program to obtain advanced education relevant to the faculty member's teaching functions. Programs leading to a graduate degree offer curricula that prepare CRNAs for the teaching role.

Proposed Policy on Payment of Stipends

It is proposed that a faculty member may be paid a stipend for living costs if attending an educational institution as a full-time student; no stipend would be available for a faculty member who is enrolled in part-time study or who is employed on a full-time basis. This policy is designated to target stipend assistance to the individuals who are most in need of such aid.

Proposed Funding Preferences

It is proposed to give funding preference first to minority faculty, second to faculty who will complete degree requirements before or by the end of the funded budget year, third to faculty who are full-time students, and fourth, to faculty who are part-time students. The preference for minority faculty will continue Department efforts to increse and retain minority faculty, who currently are underrepresented in institutions for the education of nurse anesthetists. The other preferences will help to ensure an outcome of trained faculty, within available resources, in the shortest time possible.

Proposed Review Criteria

Applications will be reviewed by staff in the Division of Nursing and in the Grants Management Office of the Bureau of Health Professions, taking into consideration:

1. The eligibility of applicants;
2. The eligibility of faculty; and
3. The extent to which an applicant meets the funding preferences.

Interested persons are invited to comment on the proposed criteria for fellows, policy on payment of stipends, funding preferences, and review criteria. Normally, the comment period would be 60 days. However, due to the need to implement any changes for the Fiscal Year 1990 award cycle, this comment period has been reduced to 30 days. All comments received on or before July 20, 1990 will be considered before the final criteria for fellows, policy on payment of stipends, funding preferences, and review criteria are established. No funds will be awarded until a final notice is published.

Written comments should be addressed to: Acting Director, Division of Nursing, Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, room 5C–26, 5600 Fishers Lane, Rockville, Maryland 20857.

All comments received will be available for public inspection and copying at the Division of Nursing, Bureau of Health Professions, at the above address, weekdays (Federal holidays excepted) between the hours of 8:30 a.m. and 5 p.m.

Application Deadline

One review cycle will be held annually for Grants for Nurse Anesthetist Faculty Fellowships. The deadline date for receipt of applications for Fiscal Year 1990 is July 30, 1990. Applications shall be considered as meeting the deadline if they are either:

(1) Received on or before the deadline, or

(2) Postmarked on or before the deadline date, and received in time for submission to the independent review group. A legibly dated receipt from a commercial carrier or U.S. Postal Service will be accepted in lieu of a postmark. Private metered postmarks shall not be acceptable as proof of timely mailing. Applications received after the deadline date will be returned.

A request to use Form PHS 6025–1, HRSA Competing Training Grant Application (OMB No. 0915–0060), and for approval of the supplemental instructions is in preparation and will be submitted to OMB.

Requests for application materials should be directed to: Grants Management Officer (A–22), Bureau of Health Professions, Health Resources and Services Administration, Parklawn Building, room 8C–26, 5600 Fishers Lane, Rockville, Maryland 20857, Telephone: (301) 443–6857.

For technical assistance and other information regarding this program, contact: Division of Nursing, Bureau of

Health Professions, Health Resources and Services Administration, Parklawn Building, room 5C-26, 5600 Fishers Lane, Rockville, Maryland 20857, (301) 443-5763.

The Catalog of Federal Domestic Assistance number is 13.907. This program is not subject to the provisions of Executive Order 12372, Intergovernmental Review of Federal Programs (as implemented through 45 CFR part 100).

Robert G. Harmon,

Administrator.

[FR Doc. 90-14185 Filed 6-11-90; 8:45 am]

BILLING CODE 4160-15-M

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction Act

The proposal of the collection of information listed has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed information collection requirement, related forms and explanatory material may be obtained by contacting the Bureau's Clearance Officer at the phone number listed below. Comments and suggestions on the requirement should be made directly to the Office of Management and Budget Interior Desk Officer at (202) 395-7340. Title 25 CFR, subchapter E, part 39—The Indian School Equalization Program, 25 U.S.C. 20008.

Title: Bureau of Indian Affairs School Equalization Program Student Membership Form

OMB Approval number: 1076-0108

Abstract: Indian School Equalization Program funds are distributed on a formula basis to all Bureau-funded Elementary and Secondary schools. Weighted student units which consist of a value for Basic and Specialized Instructional and Residential Programs are used to calculate the distribution of funds. About ⅔ of the Bureau-funded schools are operated through contracts or grants with Indian tribes, and are required to submit this data to receive funding.

Bureau Form Number: Un-numbered

Frequency: Annually

Description of Respondents: Elementary and Secondary Students

Estimated Completion Time: 5 minutes

Annual Response: 13,500

Annual Burden Hours: 1,121

Bureau Clearance Officer: Gail Sheridan, (202) 208-2685.

Dated: June 8, 1990.

Betty Walker,

Acting Deputy to the Assistant Secretary—Indian Affairs/Director (Indian Education Programs).

[FR Doc. 90-14238 Filed 6-19-90; 8:45 am]

BILLING CODE 4310-02-M

Bureau of Land Management

[AA-680-00-4130-02]

Information Collection Submitted to the Office of Management and Budget for Review Under the Paperwork Reduction

The proposal for the collection of information listed below has been submitted to the Office of Management and Budget for approval under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35). Copies of the proposed collection of information and related forms may be obtained by contacting the Bureau's Clearance Officer at the phone number listed below. Comments and suggestions on the proposal should be made directly to the Bureau of Clearance Officer and to the Office of Management and Budget, Paperwork Reduction Project (1004-0025), Washington, DC 20503, telephone 202-395-7340.

Title: Application for Survey of Mining Claims, 43 CFR 3861.1-1.

OMB approval number: 1004-0025.

Abstract: The Mining Law of 1872 (30 U.S.C. 21-54) requires the issuance of a patent where the requirements of law have been met and a mineral patent application has been filed. A mineral survey of the mining claims must be submitted as part of the mineral patent application. Form 3860-5 is an application for the surveying by an authorized U.S mineral surveyor.

Bureau Form Number: 3860-5.

Frequency: Once.

Description of respondents: Respondents may range from an individual to multi-national corporations.

Estimated completion time: 4 hours.

Annual responses: 85.

Annual burden hours: 340.

Bureau Clearance Officer (Alternate): Gerri Jenkins, (202) 653-8853.

Dated: May 18, 1990.

Adam A. Sokoloski,

Deputy Assistant Director for Energy and Mineral Resources.

[FR Doc. 90-14236 Filed 6-19-90; 8:45 am]

BILLING CODE 4130-84-M

[UT-060-0-4380-13]

Closure of Public Lands; Utah

June 12, 1990.

AGENCY: Bureau of Land Management, Interior.

ACTION: Emergency ORV Closure Order.

SUMMARY: Severe resource damage is occurring to soils, vegetation, water quality, cultural resources and scenic values as a result of heavy off-road vehicle activity in Comb Wash, in the San Juan Resource Area, Moab District, Utah.

In order to curtail this damage, the Moab District Manager has made a decision to impose an emergency ORV Closure order, as provided in 43 CFR, 8341.2, against the use of vehicles, including bicycles, anywhere off the San Juan County road system, the road into Mule Canyon, and other designated and marked as open routes within the confines of the Comb Wash drainage, bounded on the north by Highway 95 and on the south by Highway 163.

This emergency closure order is in effect immediately upon publication in the **Federal Register** and will remain in effect until full off-road vehicle designations are established and implemented.

The grazing permittees using this area are exempt from this order, providing their activities are restricted to those allowed by the terms and conditions of their grazing permits.

Any person who violates or fails to comply with this order is subject to arrest, conviction and/or punishment. Such punishment may be a fine of not more than $1000, or imprisonment for not longer than 12 months, or both, as provided in 43 CFR 8340.0-7.

Gene Nodine,

District Manager.

[FR Doc. 90-14228 Filed 6-19-90; 8:45 am]

BILLING CODE 4310-DQ-M

Fish and Wildlife Service

Availability of Draft Recovery Plan for Hymenoxys Acaulis Var. Glabra (Lakeside Daisy) for Review and Comment

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Notice of availability and public comment period.

SUMMARY: The U.S. Fish and Wildlife Service announces the availability for public review of a draft recovery plan for *Hymenoxys acaulis* var. *glabra* (Lakeside daisy). This plant is known

from only one naturally occurring population in Ottawa County, Ohio, where it is found scattered within an area of about three square miles in the abandoned portions of a quarry on the Marblehead Peninsula. The species has been extirpated from Illinois; however, it has recently been introduced into three sites within the historic range of Will and Tazewell Counties. Lakeside daisy is also known from Manitoulin Island and the Bruce Peninsula in southern Ontario, where it is found at 13 sites. The Service solicits review and comments from the public on this draft plan.

DATES: Comments on the draft recovery plan must be received on or before July 20, 1990, to receive consideration by the Service.

ADDRESSES: Persons wishing to review the draft recovery plan may examine a copy during normal business hours at the Twin Cities Regional Office, Division of Endangered Species, U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111, telephone 612/725–3276, FTS 725–3276, the Reynoldsburg Field Office, 6950–H Americana Parkway, Reynoldsburg, Ohio 43068, telephone 614/469–6923, FTS 943–6923, and the Rock Island Field Office, 1830 2nd Avenue, Rock Island, Illinois 61201, telephone 309/793–5800, FTS 782–5800. Persons wishing to obtain a copy of the draft recovery plan should contact the Twin Cities Regional Office. Written comments and materials regarding the plan should be mailed to the Twin Cities Office. All comments and materials received will be available for public inspection, by appointment, during normal business hours at that office for the duration of the comment period.

FOR FURTHER INFORMATION CONTACT: William F. Harrison, at the above Twin Cities Regional Office address (612/725–3276; FTS 725–3276).

SUPPLEMENTARY INFORMATION:

Background

Restoring endangered or threatened animals and plants to the point where they are again secure, self-sustaining members of their ecosystems is a primary goal of the U.S. Fish and Wildlife Service's endangered species program. To help guide the recovery effort, the Service is working to prepare recovery plans for most of the listed species native to the United States. Recovery plans describe actions considered necessary for conservation of the species, criteria for recognizing the recovery levels for downlisting or delisting them, and initial estimates of times and costs to implement the recovery measures needed.

The Endangered Species Act of 1973 (Act), as amended (16 U.S.C. 1531 *et seq.*), requires the development of recovery plan for listed species unless such a plan would not promote the conservation of a particular species. Section 4(f) of the Act as amended in 1988 requires that public notice and an opportunity for public review and comment be provided during recovery plan development. The Service will consider all information presented during a public comment period prior to approval of each new or revised recovery plan. The Service and other Federal agencies will also take these comments into account in the course of implementing approved recovery plans.

Hymenoxys acaulis var. *glabra* was listed as a threatened species under the Act on June 23, 1988 (53 FR 23742). Historically this species occurred on the dry limestone prairies of the Marblehead Peninsula but, because of habitat alteration, its range has been reduced to an area of about three square miles. The Ohio Department of Natural Resources recently acquired 19 acres, which represents the only protected naturally occurring population, and has introduced lakeside daisy at Kelly's Island State Park, about five air miles from the Marblehead Peninsula population. The plan, once known from Tazewell and Will counties in Illinois, has been extirpated there. It has been introduced at two sites in Will County and one site in Tazewell County.

Lakeside daisy is an herbaceous spring-blooming perennial with a short, thick taproot and a stout branching caudex. The leaves are thick, spatulate, one-nerved, and form a rosette. The peduncle will extend upwards from 2 to 10 inches and bear a solitary head with 10–30 radiating yellow rays. Most plants in an area will flower at the same time, from late April to mid-May, and produce a radiant mass of yellow flowers. The recovery plan outlines strategies to protect and manage adequate habitat where the species occurs, establish additional populations within its historic range, investigate the response of the plant to various management actions, monitor the status of known populations, develop public awareness, and implement educational programs about the species. The goal of the recovery plan is to place 475 acres of the Marblehead Peninsula population in Ottawa County, Ohio, under protective management, establish a stable population in two geographically distinct sites within the historic range in Illinois, and maintain the restored populations for 25 years.

Public Comments Solicited

The Service solicits written comments on this recovery plan. All comments received by the date specified above will be considered prior to approval of the plan.

Authority

The authority for this action is section 4(f) of the Endangered Species Act, 16 U.S.C. 1533(f).

Dated: June 14, 1990.

James C. Gritman,

Regional Director.

[FR Doc. 90–14237 Filed 6–19–90; 8:45 am]

BILLING CODE 4310–55–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337–TA–314]

Certain Battery-Powered Ride-on Toy Vehicles and Components Thereof; Investigation

AGENCY: U.S. International Trade Commission.

ACTION: Institution of investigation pursuant to 19 U.S.C. 1337.

SUMMARY: Notice is hereby given that a complaint was filed with the U.S. International Trade Commission on May 15, 1990 under section 337 of the Tariff Act of 1930, as amended, 19 U.S.C. 1337, on behalf of Kransco, 160 Pacific Avenue, San Francisco, California 94123. A supplement to the complaint was filed on June 8, 1990. The complaint, as amended, alleges violations of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, and the sale within the United States after importation of certain battery-powered ride-on toy vehicles and components thereof by reason of alleged infringement of (1) Claim 1 of U.S. Letters Patent Des. 299,666, (2) claims 1, 2, 3, 4, 5, and 6 of U.S. Letters Patent 4,709,958, (3) claims 1, 2, 3, and 4 of U.S. Letters Patent 4,639,646, (4) claim 1 of U.S. Letters Patent Des. 292,009, and (5) claims 1, 2, 4, 8, 9, 16, and 19 of U.S. Letters Patent 4,558,263; and that there exists an industry in the United States as required by subsection (a)(2) of section 337.

The complainant request that the Commission institute an investigation and, after a full investigation, issue a permanent exclusion order and permanent cease and desist orders.

ADDRESSES: The complaint, except for any confidential information contained therein, is available for inspection during official business hours (8:45 a.m.

to 5:15 p.m.) in the Office of the Secretary. U.S. International Trade Commission, 500 E Street SW., Room 112, Washington, DC 20436, telephone 202–252–1802. Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–252–1810.

FOR FURTHER INFORMATION CONTACT: Daniel M. Duty, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, telephone 202–252–1581.

Authority: The authority for institution of this investigation is contained in section 337 of the Tariff Act of 1930, as amended, and in section 210.12 of the Commission's Interim Rules of Practice and Procedure, 19 CFR 210.12.

Scope of Investigation

Having considered the complaint, the U.S. International Trade Commission, on June 12, 1990, Ordered That—

(1) Pursuant to subsection (b) of section 337 of the Tariff Act of 1930, as amended, an investigation be instituted to determine:

(a) Whether there is a violation of subsection (a)(1)(B) of section 337 in the importation into the United States, the sale for importation, or the sale within the United States after importation of certain battery-powered ride-on toy vehicles and components thereof by reason of alleged infringement of: (1) Claim 1 of U.S. Letters Patent Des. 299,666, (2) claims, 1, 2, 3, 4, 5, and 6 of U.S. Letters Patent 4,709,958, (3) claims 1, 2, 3, and 4 of U.S. Letters Patent 4,639,646, (4) claim 1 of U.S. Letters Patent Des. 292,009, and (5) claims 1, 2, 4, 8, 9, 16, and 19 of U.S. Letters Patent 4,558,263, and whether there exists an industry in the United States as required by subsection (a)(2) of section 337.

(2) For the purpose of the investigation so instituted, the following are hereby named as parties upon which this notice of investigation shall be served:

(a) The complainant is—Kransco, 160 Pacific Avenue, San Francisco, California 94123.

(b) The respondent is the following company alleged to be in violation of section 337, and is the party upon which the complaint is to be served: Chien Ti Enterprise Co., Ltd., No. 13, Lane 227, Fu Ying Road, Hsin-Chuang, Taipei, Taiwan.

(c) Daniel M. Duty, Esq., Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Room 401L, Washington, DC 20436, who shall be the Commission investigative attorney, party to this investigation; and

(3) For the investigation so instituted, Janet D. Saxon, Chief Administrative Law Judge, U.S. International Trade Commission, shall designate the presiding Administrative Law Judge.

Responses to the complaint and the notice of investigation must be submitted by the named respondent in accordance with § 210.21 of the Commission's Interim Rules of Practice and Procedure, 19 CFR 210.21. Pursuant to §§ 201.16(d) and 210.21(a) of the Commission's Rules (19 CFR 201.16(d) and 210.21(a)), such responses will be considered by the Commission if received not later than 20 days after the date of service of the complaint. Extensions of time for submitting responses to the complaint will not be granted unless good cause therefor is shown.

Failure of a respondent to file a timely response to each allegation in the complaint and in this notice may be deemed to constitute a waiver of the right to appear and contest the allegations of the complaint and this notice, and to authorize the administrative law judge and the Commission, without further notice to the respondents, to find the facts to be as alleged in the complaint and this notice and to enter both an initial determination and a final determination containing such findings, and may result in the issuance of a limited exclusion order or a cease and desist order or both directed against such respondent.

By order of the Commission.

Issued: June 12, 1990.

Kenneth R. Mason,

Secretary.

[FR Doc. 90–14259 Filed 6–19–90; 8:45 am]

BILLING CODE 7020–02–M

[Investigation No. 337–TA–312]

Certain Dynamic Random Access Memories, Static Random Access Memories, Components Thereof, and Products Containing Same; Commission Determination Not To Review Initial Determination Designating the Investigation More Complicated

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Commission has determined not to review the presiding administrative law judge's (ALJ's) initial determination (ID) designating the above-captioned investigation more complicated.

FOR FURTHER INFORMATION CONTACT: Stephen A. McLaughlin, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202–252–1095.

SUPPLEMENTARY INFORMATION: On May 8, 1990, respondents Hyundai Electronics Industries Co., Ltd. and Hyundai Electronics America, Inc. (Hyundai) filed a motion (Motion No. 312–2) seeking an order designating the investigation more complicated. The Commission investigative attorney filed a response in support of Hyundai's motion. Complainant SSG–Thomson Microelectronics, Inc., filed a response opposing Hyundai's motion.

On May 16, 1990, the presiding (ALJ) issued an ID (Order No. 1) designating the investigation more complicated. No petitions for review or comment from government agencies were received.

The Commission determined not to review the ID. The case has been designated more complicated due to the large number of patents involved, the complexity of the factual and legal issues that need to be resolved, and the need for time-consuming discovery.

Copies of the ALJ's ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 701 E Street NW., Washington DC 20436, telephone 202–252–1000.

Hearing-impaired individuals are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–252–1810.

By order of the Commission.

Issued: June 14, 1990.

Kenneth R. Mason,

Secretary.

[FR Doc. 90–14258 Filed 6–1–90; 8:45 am]

BILLING CODE 7020–02–M

[Investigation No. 337–TA–276]

Certain Erasable Programmable Read Only Memories, Components Thereof, Products Containing Such Memories, and Processes for Making Such Memories; Commission Decision Denying Petitions for Advisory Opinions

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Commission has denied two petitions for advisory opinions filed by Microchip Technology, Inc., a

respondent in the above-captioned investigation.

FOR FURTHER INFORMATION CONTACT: Judith M. Czako, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202–252–1093.

SUPPLEMENTARY INFORMATION: The authority for the Commission's determination is contained in section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) and in § 211.54 of the Commission's Interim Rules of Practice and Procedure, 19 CFR 211.54.

On March 16, 1989, the Commission issued its final determination in this investigation. The Commission determined, *inter alia*, that there was a violation of section 337 in the unlicensed importation and sale of certain EPROMs manufactured abroad for Microchip Technology Inc. which infringe valid U.S. patents owned by complainant Intel, including the '394 and '050 patents. The Commission determined that a limited exclusion order and cease and desist orders were the appropriate remedy. The Commission's determination and orders became final on May 22, 1989, the President having determined to take no action with respect to them.

On September 13, 1989, respondent Microchip filed two petitions for advisory opinions, concerning whether its redesigned EPROMs infringe the '394 and '050 patents. Complainant in the investigation, Intel Corporation, and the Commission investigative attorney filed responses objecting to the petitions. Microchip filed a reply to the oppositions, which was opposed by Intel. Intel aslo asked that the Commission not accept the reply.

The Commission having considered the petitions, the opposition thereto, and Microchip's reply and the opposition thereto, has determined to strike the reply from the record, and deny the petitions for advisory opinions for failure to comply with the requirements for petitions for advisory opinions set forth in the Commission's rules and previous decisions.

Notice of this investigation was published in the **Federal Register** of September 16, 1987 (52 FR 35004).

Copies of the Commission's Order and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–252–1000. Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–252–1810.

By order of the Commission.

Issued: June 11, 1990.

Kenneth R. Mason,

Secretary.

[FR Doc. 90–14254 Filed 6–19–90; 8:45 am]

BILLING CODE 7020–02–M

[Investigation No. 337–TA–308]

Certain Key Blanks for Keys of High Security Cylinder Locks; Decision Not To Review Initial Determination Terminating Investigation as to Respondent Action Security Products, Inc., on the Basis of a Consent Order; Issuance of Consent Order

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined not to review an initial determination (ID) (Order No. 6) issued on May 24, 1990, by the presiding administrative law judge (ALJ) in the above-captioned investigation terminating the investigation as to respondent Action Security Products, Inc. on the basis of a consent order.

FOR FURTHER INFORMATION CONTACT: Marc A. Bernstein, Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–252–1087.

SUPPLEMENTARY INFORMATION: On May 24, 1990, the ALJ issued an ID granting the joint motion of complainant Medeco Security Locks, Inc. and respondent Action Security Products, Inc. ("ASP") to terminate the investigation as to ASP on the basis of a proposed consent order. Notice of the ID was published in the **Federal Register**, and comments of interested persons were solicited. 55 FR 22109 (May 31, 1990). No petitions for review of the ID were filed and no government agencies or members of the public submitted comments. This action is taken under the authority of section 337 of the Tariff Act of 1930, 19 U.S.C. 1337, and Commission interim rule 210.53(h), 19 CFR 210.53(h).

Copies of the ID and all other nonconfidential documents filed in connection with this investigation are available for inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–252–1000. Hearing-impaired persons are advised that information on this matter can be obtained by contacting the Commission's TDD terminal on 202–252–1810.

By order of the Commission.

Issued: June 13, 1990.

Kenneth R. Mason,

Secretary.

[FR Doc. 90–14257 Filed 6–19–90; 8:45 am]

BILLING CODE 7020–02–M

[Investigations Nos. 731–TA–458–460 (Preliminary)]

Polyethylene Terephthalate Film, Sheet, and Strip From Japan, the Republic of Korea, and Taiwan

Determinations

On the basis of the record [1] developed in the subject investigations, the Commission determines,[2] pursuant to section 733(a) of the Tariff Act of 1930 (19 U.S.C. 1673b(a)), that there is a reasonable indication that an industry in the United States is materially injured by reason of imports from Japan and the Republic of Korea (Korea) of polyethylene terephthalate (PET) film, sheet, and strip [3] that are alleged to be sold in the United States at less than fair value (LTFV). The Commission also determines that there is no reasonable indication that an industry in the United States is materially injured or threatened with material injury, or that the establishment of an industry in the United States is materially retarded, by reason of imports from Taiwan of PET film, sheet, and strip [3] that are alleged to be sold in the United States at LTFV. The subject product is provided for in subheading 3920.62.00 of the Harmonized Tariff Schedule of the United States (previously under item 771.43 of the former Tariff Schedules of the United States).

Background

On April 27, 1990, a petition was filed with the Commission and the Department of Commerce by E.I. Du

[1] The record is defined in § 207.2(h) of the Commission's Rules of Practice and Procedure (19 CFR 207.2(h)).

[2] Chairman Brunsdale not participating.

[3] The product covered by these investigations is all gauges of raw, pretreated, or primed polyethylene terephthalate film, sheet, and strip, whether extruded or coextruded. The films excluded from the scope of these investigations are metallized films and other finished films that have had at least one of their surfaces modified by the application of a performance-enhancing resinous or inorganic layer more than 0.00001 inch (0.254 micrometer) thick.

Pont de Nemours & Co., Hoechst Celanese Corp., and ICI Americas, Inc., alleging that an industry in the United States is materially injured or threatened with material injury by reason of LTFV imports of PET film, sheet, and strip from Japan, Korea, and Taiwan. Accordingly, effective April 27, 1990, the Commission instituted preliminary antidumping investigations Nos. 713–TA–458–460 (Preliminary).

Notice of the institution of the Commission's investigations and of a public conference to be held in connection therewith was given by posting copies of the notice in the Office of the Secretary, U.S. International Trade Commission, Washington, DC, and by publishing the notice in the **Federal Register** of May 7, 1990 (55 FR 18969). The conference was held in Washington, DC, on May 18, 1990, and all persons who requested the opportunity were permitted to appear in person or by counsel.

The Commission transmitted its determinations in these investigations to the Secretary of Commerce on June 1, 1990. The views of the Commission are contained in USITC Publication 2292 (June 1990), entitled "Polyethylene terephthalate film, sheet, and strip from Japan, the Republic of Korea, and Taiwan: Determinations of the Commission in Investigations Nos. 731–TA–458–460 (Preliminary) Under the Tariff Act of 1930, Together With the Information Obtained in the Investigations."

By order of the Commission.

Issued: June 13, 1990.

Kenneth R. Mason,

Secretary.

[FR Doc. 90–14256 Filed 6–19–90; 8:45 am]

BILLING CODE 7020–02–M

[Investigation No. 337–TA–290, Enforcement Proceeding]

Certain Wire Electrical Discharge Machining Apparatus and Components Thereof; Institution of Formal Enforcement Proceeding

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the Commission has docketed a complaint and instituted a formal enforcement proceeding relating to the cease and desist orders issued in the above-captioned investigation on March 9, 1990.

FOR FURTHER INFORMATION CONTACT: Craig L. McKee, Esq., Office of the General Counsel, U.S. International Trade Commission, telephone 202–252–1117.

SUPPLEMENTARY INFORMATION: The authority for the Commission's action is contained in section 337 of the Tariff Act of 1930 (19 U.S.C. 1337) and in § 211.56(c) of the Commission's Interim Rules of Practice and Procedure, 19 CFR 211.56(c).

Concurrently with the issuance of this Notice, the Commission caused the docketing of the complaint with the Secretary of the Commission. The Complaint was filed by the Commission's Office of Unfair Import Investigations. The Complaint is published as an addendum to this Notice. The Complaint alleges possible violations of cease and desist orders issued by the Commission on March 9, 1990, against Respondents Sodick, Inc., KGK International Corporation, Yamazen USA, Inc., and Bridgeport Machines, Inc.

The following were named as parties to the proceeding:

(a) Sodick Co., Ltd., 1–5–1 Shin-Yokohama, Kouhoku-Ku, Yokohama, Kanagawa 222, Japan, a respondent in the investigation;

(b) Sodick, Inc., 2100 Golf Road, Rolling Meadows, Illinois 60008, a respondent in the investigation;

(c) KGK International Corporation, 543 W. Algonquin Road, Arlington Heights, Illinois 60005, a respondent in the investigation;

(d) Yamazen USA, Inc., 1130 Dominguez Street, Carson, California 90746, a respondent in the investigation;

(e) Bridgeport Machines, Inc., 500 Lindley Street, Bridgeport, Connecticut 06606, a respondent in the investigation;

(f) Elox Corporation, Griffith Street, P.O. Box 220, Davidson, North Carolina 28036, a complainant in the investigation;

(g) A.G. fur Industrielle Elektronik AGIE, Losone bei Locarno, CH–6616 Losone, Switzerland, a complainant in the investigation; and

(h) A Commission investigative attorney to be designated by the Director, Office of Unfair Import Investigations.

In accordance with § 211.56 of the Commission's Interim Rules of Practice and Procedure (19 CFR 211.56), responses to the complaint must be filed by the parties within fifteen (15) days after the date of receipt of the complaint.

Copies of the Commission's Order and all other nonconfidential documents filed in connection with this formal enforcement proceeding are available for inspection during official buisness hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202–252–1000. Hearing-impaired persons are advised that information on the matter can be obtained by contacting the Commission's TDD terminal on 202–252–1810.

By order of the Commission.

Issued: June 13, 1990.

Kenneth R. Mason,

Secretary.

Order

On March 9, 1990, the Commission issued its final determination in the above-captioned investigation. The Commission determined that there was a violation of section 337 of the Tariff Act of 1930, as amended (19 U.S.C. § 1337), in the unlicensed importation and sale of certain wire electrical discharge machining apparatus ("wire EDM machines") by, *inter alia*, respondents Sodick Co., Ltd., Sodick Inc., KGK International Corporation, Yamazen USA, Inc., and Bridgeport Machines, Inc. The Commission determined that a limited exclusion order and four cease and desist orders were the appropriate remedy. Cease and desist orders were issued to Sodick Inc., KGK International Corporation, Yamazen USA, Inc., and Bridgeport Machines, Inc. The Commission's determination and orders became final a May 8, 1990, the President having taken no action with respect to the Commission's determination and orders.

In parallel litigation involving the '163 patent in federal district court before Judge Milton I. Shadur of the U.S. District Court for the Northern District of Illinois, Sodick Co., Ltd. moved for a summary judgment that a newly designed Sodick wire EDM machine was non-infringing and sought a preliminary injunction to enjoin Complainant A.G. fur Industrielle Elektronik AGIE from initiating an enforcement proceeding before the Commission regarding the new design. On May 9, 1990, Judge Shadur ordered, *inter alia*, that with respect to this new design, "Agie, its officers, agents, servants, employees and attorneys and all persons in active concert or participation with any of them * * * are hereby preliminarily enjoined * * * from initiating or causing others to initiate any enforcement proceeding in the ITC * * *."

Inasmuch as Respondents are not seeking an advisory option from the Commission regarding their new wire EDM machine design and have obtained an order enjoining Complainants from initiating an enforcement proceeding in the Commission, the Commission has determined to authorize the docketing of a Complaint to institute a formal enforcement proceeding to determine

whether the Respondents have imported newly designed wire EDM machines that infringe the '163 patent in violation of the Commission's March 9, 1990, cease and desist orders and, if so, what enforcement measures would be appropriate. The formal enforcement proceeding is being initiated by the Commission on its own motion and not pursuant to a request by or discussion with Complainants.

The requirement under Interim Rule 211.56(c) that the Complaint specifically allege violation of a Commission order is hereby waived. Pursuant to Interim Rule 211.52, the Commission is continuing the administrative protective order previously issued in the investigation. After receiving responses to the Complaint, the Commission will determine whether the enforcement action should be assigned to an Administrative Law Judge for hearing and other proceedings. In the event that the Commission, after a formal enforcement investigation, finds that there has been a violation of the Commission's orders in the importation of the newly designed Sodick wire EDM machines into the United States, or in their sale in the United States, the Commission may modify the Commisson's exclusion and cease and desist orders under Interim Rule 211.56(c)(3) in any manner necessary to prevent the unfair practices which were originally the basis for issuing such order, may impose civil penalties pursuant to 19 U.S.C. 1337(f), and may bring a civil action in the United States district court pursuant to 19 CFR 211(b) (and 19 U.S.C. 1337(f)) requesting the recovery of such civil penalties or the issuance of a mandatory injunction incorporating relief sought by the Commission.

The Commission having determined that institution of a formal enforcement proceeding is appropriate, *it is hereby Ordered that*—

1. Pursuant to Commission Interim Rule 211.56(c), 19 CFR 211.56(c), a formal enforcement proceeding is instituted to determine whether Sodick Co., Ltd., Sodick Inc., KGK International Corporation, Yamazen USA, Inc., and/or Bridgeport Machines, Inc. are in violation of the Commission's cease and desist orders issued on March 9, 1990, in the above-captioned investigation and what if any enforcement measures are appropriate.

2. For purposes of the formal enforcement proceeding so instituted, the following are named as parties:

(a) Sodick Co., Ltd., 1–5–1 Shin-Yokohama, Kouhoku-Ku, Yokohama, Kanagawa 222, Japan, a respondent in the investigation;

(b) Sodick, Inc., 2100 Golf Road, Rolling Meadows, Illinois 60008, a respondent in the investigation;

(c) KGK International Corporation, 543 W. Algonquin Road, Arlington Heights, Illinois 60005, a respondent in the investigation;

(d) Yamazen USA, Inc., 1130 Dominguez Street, Carson, California 90746, a respondent in the investigation;

(e) Bridgeport Machines, Inc., 500 Lindley Street, Bridgeport, Connecticut 06606, a respondent in the investigation;

(f) Elox Corporation, Griffith Street, P.O. Box 220, Davidson, North Carolina 28036, a complainant in the investigation;

(g) A.G. fur Industrielle Elektronik AGIE, Losone bei Locarno, CH–6616 Losone, Switzerland, a complainant in the investigation; and

(h) A Commission investigative attorney to be designated by the Director, Office of Unfair Import Investigations.

3. Pursuant to Commission Interim Rule 211.52, 19 CFR 211.52, the Commission is continuing the administrative protective order previously issued in the investigation.

4. The Secretary shall:

(a) Docket the attached Complaint for a formal enforcement proceeding;

(b) Serve a copy of the Complaint on each of the above-named parties, and advise each such party of the provisions of Commission Interim Rule 211.56(c) concerning responses to the Complaint and replies to responses;

(c) serve a copy of this Order upon each party to the formal enforcement proceeding and upon each party of record in the investigation; and

(d) publish notice of this Order in the **Federal Register** along with an addendum consisting of the attached Complaint.

By order of the Commission.

Issued: June 13, 1990.

Kenneth R. Mason,

Secretary.

Complaint

This complaint under sections 333 and 337 of the Tariff Act of 1930 as amended (19 U.S.C. 1333, 1337) and U.S. International Trade Commission Interim Rule 211.56(c) (19 CFR 211.56(c)) concerns the possible violation of the Commissoin cease and desist orders issued on March 9, 1990, in Certain Wire Electrical Discharge Machinging Apparatus and Components Thereof, Inv. No. 337–TA–290. The cease and desist orders were issued to Sodick, Inc., KGK International Corporation, Yamazen USA, Inc., and Bridgeport Machines, Inc.

The following is alleged:

I. Jurisdiction

1. Jurisdiction over the subject matter of this complaint and over the proposed parties is derived from sections 333 and 337 of the Tariff Act of 1930 as amended (19 U.S.C. 1333, 1337).

II. Parties To Be Named

2. Sodick Co., Ltd. ("Sodick Japan"), a respondent in the investigation, located at 1–5–1 Shin-Yokohama, Kouhoku-Ku, Yokohama, Kanagawa 222, Japan, designs, manufactures, and exports wire electrical discharge machining apparatus ("wire EDM machines") and replacement parts.

3. Sodick, Inc. ("Sodick US"), a respondent in the investigation, located at 2100 Golf Road, Rolling Meadows, Illinois 60008, is a wholly-owned subsidiary of Sodick Japan, and sells, distributes, and services wire EDM machines and replacement parts manufactured by Sodick Japan.

4. KGK International Corporation ("KGK US"), a respondent in the investigation, located at 543 W. Algonquin Road, Arlington Heights, Illinois 60005, is the midwestern distributor of Sodick wire EDM machines.

5. Yamazen USA, Inc. ("Yamazen US"), a respondent in the investigation, located at 1130 Dominguez Street, Carson, California 90746, is the West Coast distributor of Sodick wire EDM machines.

6. Bridgeport Machines, Inc. ("Bridgeport"), a respondent in the investigation, located at 500 Lindley Street, Bridgeport, Connecticut 06606, is the East Coast distributor of Sodick wire EDM machines and also sells and distributes Sodick equipment and parts under the "McWilliams" name through its division, McWilliams Machinery Sales Co.

7. Elox Corporation ("Elox"), a complainant in the investigation, is located at Griffith Street, P.O. Box 220, Davidson, North Carolina 28036.

8. A.G. fur Industrielle Elektronik AGIE ("Agie"), a complainant in the investigation, is located at Losone bei Locarno, CH–6616 Losone, Switzerland.

III. The Underlying Commission Investigation

9. On February 27, 1989, the Commission instituted Investigation No. 337–TA–290 pursuant to section 337 of the Tariff Act of 1930 as amended (19 U.S.C. 1337) based upon a complaint, as supplemented, filed by Elox and Agie alleging violation of section 337 by Sodick Japan, Sodick US, KGK Corporation ("KGK Japan"), KGK US, Yamazen Co., Ltd. ("Yamazen Japan"), Yamazen US, Maruka Machinery Co., Ltd., Maruka Machinery Corporation of America, and Bridgeport. Specifically, Complainants alleged that these Respondents were importing into and selling in the United States certain wire

EDM machines and components thereof manufactured by Sodick Japan that infringed U.S. Letters Patent 3,928,163 (the " '163 Patent").

10. Following a hearing on the merits, in which Sodick Japan, Sodick US, KGK Japan, KGK US, Yamazen Japan, Yamazen US, and Bridgeport (the "Sodick Respondents") participated, Chief Adminstrative Law Judge Janet D. Saxon issued an Initial Determination ("ID") on December 7, 1990, finding that there was a violation of section 337 in connection with the Sodick Respondents' importation and sale of Sodick wire EDM machines that infringe claims 1, 7, 9, 20, and 22 of the '163 patent.

11. The Commission reviewed certain issues addressed in the ID and ultimately concluded that there was a violation of section 337 in the Sodick Respondents' importation, sale for importation, or sale in the United States of infringing EDM machines. The Commission affirmed the Administrative Law Judge's finding that Sodick's EDM machines infringe claims 1, 7, 9, 20, and 22 of the '163 patent under the doctrine of equivalents because:

> the fluid discharged at the outlet of the [Sodick devices] is alongside of the electrode and in contact with the wire electrode, and sufficiently close to parallel to the axis of the electrode so as to achieve the objective of minimizing the transverse force components on the electrode, *i.e.*, the flow is functionally equivalent to parallel to the electrode.

(Commission Opinion at 12).

12. On March 9, 1990, the Commission issued a limited exclusion order barring from entry into the United States "[w]ire electrical discharge machining apparatus, in assembled or unassembled form, manufactured by or on behalf of respondent Sodick Co., Ltd." which infringe claims 1, 7, 9, 20, or 22 of the '163 patent for the remaining term of the patent, except under license from the patent owner.

13. In addition, on March 9, 1990, the Commission issued cease and desist orders to Sodick US, KGK US, Yamazen US, and Bridgeport prohibiting them from marketing, distributing, offering for sale, selling, or otherwise transferring in the United States imported wire electrical discharge machining apparatus, in assembled or unassembled form, covered by claims 1, 7, 9, 20, or 22 of the '163 patent, for the remaining term of the patent, except under license from Complainants.

14. The provisions of the cease and desist orders also apply to the Respondents' "principals" and "stockholders". As noted above, Sodick US is a wholly-owned subsidiary of Sodick Japan.

IV. Activities and Proceedings Subsequent to the Commission's Orders

15. Agie and Sodick Japan, Sodick US, and KGK US (collectively the "Sodick Defendants") are also engaged in litigation involving the '163 patent in federal district court before Judge Milton I. Shadur of the U.S. District Court for the Northern District of Illinois (the "district court action").

16. After the Commission issued its exclusion and cease and desist orders, Respondents' counsel advised Complainants' counsel that Respondents had developed and installed on their wire EDM machines a new wire guide and flushing assembly which in Respondents' opinion did not infringe claims 1, 7, 9, 20, or 22 of the '163 patent. (The Sodick EDM machines with the new wire guide and flushing assemblies are referred to herein as the "New Design").

17. The Sodick Defendants moved in the district court action for a summary judgment that their New Design was non-infringing and sought a preliminary injunction to enjoin Complainant from initiating an enforcement proceeding before the Commission regarding the New Design.

18. After consideration of the Sodick Defendants' motion, Judge Shadur, on May 9, 1990, found a "reasonable likelihood" that the Sodick Defendants would prevail on their claim that the New Design did not infringe the '163 patent, and held that the Sodick Defendants could be "irreparably harmed by the threat and danger that" Agie might initiate any proceedings before the Commission with respect to the New Design. Judge Shadur then ordered, *inter alia*, that "Agie, its officers, agents, servants, employees and attorneys and all persons in active concert or participation with any of them * * * are hereby preliminarily enjoined * * * from initiating or causing others to initiate any enforcement proceeding in the ITC * * *."

V. Possible Violation of the Commission's Cease and Desist Orders

19. The Sodick Respondents have not sought an advisory opinion from the Commission regarding the issue of whether or not the Respondents' New Design infringes claims 1, 7, 9, 20, or 22 of the '163 patent.

20. Complainants are prohibited by the district court's order from asking the Commission to initiate an enforcement proceeding in connection with the New Design and they have not done so.

21. At this time, the Commission does not possess sufficient information to determine whether the importation and sale of the New Design by Sodick Japan, Sodick US, KGK US, Yamazen US, and Bridgeport is in violation of the Commission's cease and desist orders. However, based upon currently available information, there is a distinct possibility that the New Design infringes claims 1, 7, 9, 20, or 22 of the '163 patent.

22. Given the distinct possibility that the Respondents' importation and sale of the New Design is in violation of the Commission's cease and desist orders, and given the Respondents' failure to seek an advisory opinion and the district court's order enjoining the Complainants from initiating or causing others to initiate an enforcement proceeding, a formal enforcement proceeding initiated by the Commission is necessary to determine whether Sodick Japan, Sodick US, KGK US, Yamazen US, and Bridgeport are violating the Commission's cease and desist orders and what, if any, enforcement measures are appropriate.

VI. Appropriate Relief

23. In the event that the Commission, after a formal enforcement proceeding, finds that there has been a violation of the Commission's orders in the importation of the New Design into the United States, or in their sale in the United States, the Commission may issue the following remedies:

(A) Modify the Commission's exclusion and cease and desist orders pursuant to 19 CFR 211.56(c)(3) in any manner necessary to prevent the unfair practices which were originally the basis for issuing such orders; and

(B) Impose civil penalties pursuant to 19 U.S.C. 1337(f) and bring a civil action in the United States district court pursuant to 19 CFR 211.56(b) (and 19 U.S.C. 1337(f)) requesting the recovery of such civil penalties or the issuance of a mandatory injunction incorporating relief sought by the Commission.

VII. Request for Institution of Enforcement Action

24. In view of the foregoing, the Office of Unfair Import Investigations requests that the Commission docket this complaint and institute formal enforcement proceedings pursuant to 19 CFR 211.56(c), to determine whether the cease and desist orders of March 9, 1990, have been violated by Sodick Japan, Sodick US, KGK US, Yamazen US, and/or Bridgeport, and what, if any, enforcement measures are appropriate.

Respectfully submitted.

Dated: June 12, 1990.

Lynn I. Levine,

Director, Office of Unfair Import Investigations, U.S. International Trade Commission, 500 E Street SW., Room 401, Washington, DC 20436.

[FR Doc. 90–14255 Filed 6–19–90; 8:45 am]

BILLING CODE 7020–02–M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 31691]

Norfolk and Western Railway Co.—Trackage Rights Exemption—Wheeling & Lake Erie Railway Co.

Wheeling & Lake Erie Railway Company has agreed to grant local trackage rights to Norfolk and Western Railway Company over 1.4-miles of track between mileposts CZ-2.1 and CZ-3.5, in Cleveland, OH. The trackage rights were to have become effective on June 11, 1990.

This notice is filed under 49 CFR 1180.2(d)(7). Petitions to revoke the exemption under 49 U.S.C. 10505(d) may be filed at any time. The filing of a petition to revoke will not stay the transaction. Pleadings must be filed with the Commission and served on: Robert J. Cooney, Norfolk and Western Railway Company, Three Commercial Place, Norfolk, VA 23510.

As a condition to the use of this exemption, any employees affected by the trackage rights will be protected pursuant to *Norfolk and Western Ry. Co—Trackage Rights—BN*, 354 I.C.C. 605 (1978), as modified in *Mendocino Coast Ry., Inc.-Lease and Operate*, 360 I.C.C. 653 (1980).

By the Commission, Jane F. Mackall, Director, Office of Proceedings.

Dated: June 8, 1990.

Noreta R. McGee,

Secretary.

[FR Doc. 90–14250 Filed 6–19–90; 8:45 am]

BILLING CODE 7035–01–M

NAITONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

Meeting; Humanities Panel

AGENCY: National Endowment for the Humanities.

ACTION: Notice of meetings.

SUMMARY: Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92–463, as amended), notice is hereby given that the following meetings of the Humanities Panel will be held at the Old Post Office, 1100 Pennsylvania Avenue, NW., Washington, DC 20506:

FOR FURTHER INFORMATION CONTACT: Catherome Wolhowe, Advisory Committee Management Officer, Alternate, National Endowment for the Humanities, Washington, DC 20506; telephone 202/786–0322.

SUPPLEMENTARY INFORMATION: The proposed meetings are for the purpose of panel review, discussion evaluation and recommendationon applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. Because the proposed meetings will consider information that is likely to disclose: (1) Trade secrets and commercial or financial information obtained from a person and privileged or confidential; (2) information of a personal nature the disclosure of which would constitute a clearly unwarranted invasion of personal privacy; or (3) information the disclosure of which would significantly frustrate implementation of proposed agency action, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee meetings, dated January 15, 1978, I have determined that these meetings will be closed to the public pursuant to subsections (c)(4), (6) and (9)(B) of section 552b of title 5, United States Code.

1. *Date:* July 9, 1990
Time: 8:30 a.m. to 5 p.m.
Room: 415
Program: This meeting will reviw applications in Museums and Historical organizations, submitted to the Division of General Programs, for projects beginning after January 1, 1991.

2. *Date:* July 9, 1990
Time: 8:30 a.m. to 6 p.m.
Room: 430
Program: This meeting will review applications for Undergraduate Education, submitted to the Office of Challenge Grants, for projects beginning after December 1, 1990.

3. *Date:* July 12–13, 1990
Time: 8:30 a.m. to 5 p.m.
Room: 415
Program: This meeting will review applications for Museums and Historical Organizations, submitted to the Office of General Programs, for projects beginning after January 1, 1991.

4. *Date:* July 13, 1990
Time: 8:30 a.m. to 6 p.m.
Room: 430
Program: This meeting will review applications for Public Outreach, submitted to the Office of Challenge Grants, for projects beginning after December 1, 1990.

5. *Date:* July 17, 1990
Time: 8:30 a.m. to 6 p.m.
Room: 415
Program: This meeting will review applications for Museums and Historical Organizations, submitted to the Office of Challenge Grants, for projects beginning after December 1, 1990.

6. *Date:* July 19–20 1990
Time: 8:30 a.m. to 5 p.m.
Room: 415
Program: This meeting will review applications for Humanities Projects in Museums and Historical Organizations, submitted to the Division of General Programs, for projects beginning after January 1, 1991.

7. *Date:* July 20, 1990
Time: 8:30 a.m. to 6 p.m.
Room: 430
Program: This meeting will review applications for Scholarship/Research, submitted to the Office of Challenge Grants, for projects beginning after December 1, 1990.

8. *Date:* July 24, 1990
Time: 8:30 a.m. to 6 p.m.
Room: 415
Program: This meeting will review applications for Museums and Historical Organizations, submitted to the Office of Challenge Grants, for projects beginning after December 1, 1990.

9. *Date:* July 26–27, 1990
Time: 8:30 a.m. to 5 p.m.
Room: 415
Program: This meeting will review applications for Humanities Projects in Museums and Historical Organizations, submitted to the Division of General Programs, for projects beginning after January 1, 1991.

Catherine Wolhowe,

Advisory Committee, Management Officer (Alternate).

[FR Doc. 90–14186 Filed 6–19–90; 8:45 am]

BILLING CODE 7536–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-354]

Public Service Electric and Gas Co.; Issuance of Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is

considering issuance of an amendment to Facility Operating License No. NPF–57, issued to Public Service Electric and Gas Company, (the licensee), for operation of the Hope Creek Generation Station, located in Salem County, New Jersey.

Identification of Proposed Action

The amendment would consist of an addition to the Technical Specifications (TS) that would authorize the storage of the spent fuel pool as 4006 spent fuel assemblies.

The amendment to the TS is responsive to the licensee's application dated October 11, 1989. The NRC staff has prepared an Environmental Assessment of the proposed action, "Environmental Assessment by the Office of Nuclear Reactor Regulation Relating to the Expansion of the Spent Fuel Pool, Facility Operating License No. NPF–57, Public Service Electric and Gas Company, Hope Creek Generating Station, Docket No. 50–354," dated June 7, 1990.

Summary of Environmental Assessment

The "Final Generic Environmental Impact Statement (FGEIS) on Handling and Storage of Spent Light Water Power Reactor Fuel" (NUREG–0575), Volumes 1–3 (1979), concluded that the environmental impact of interim storage of spent fuel was negligible and the cost of the various alternatives reflects the advantage of continued generation of nuclear power with the accompanying spent fuel storage. Because of the differences in design, the FGEIS recommended evaluating spent fuel pool expansions on a case-by-case basis.

For Hope Creek Generating Station, the expansion of the storage capacity of the spent fuel pool will not create any significant additional radiological effects or non-radiological environmental impacts beyond those assessed in the Commission's Final Environmental Statement (FES) issued in December 1984 related to the operation of Hope Creek Generating Station, and in the Safety Evaluation Report issued October 1984 in support of a license amendment concerning storage capacity.

The occupational radiation dose for the proposed operation of the expanded spent fuel pool is estimated to be less than one percent of the total annual occupational radiation exposure for this facility.

Finding of No Significant Impact

The staff has reviewed the proposed spent fuel pool expansion to the facility relative to the requirements set forth in 10 CFR part 51. Based on this assessment, the staff concludes that there are no significant radiological or non-radiological impacts associated with the proposed action and that the issuance of the proposed amendment to the license will have no significant impact on the quality of the human environment. Therefore, pursuant to 10 CFR 51.31, no environmental impact statement needs to be prepared for this action.

For further details with respect to this action see (1) The application for amendment dated October 11, 1989, (2) the FGEIS on Handling and Storage of Spent Light Water Power Reactor Fuel (NUREG–0575), (3) the FES for Hope Creek Generating Station dated December 1984, and (4) the Environmental Assessment dated June 7, 1990.

These documents are available for public inspection at the Commission's Public Document Room, 2120 L Street NW., Washington, DC 20555 and at the Pennsville Public Library, 190 S. Broadway, Pennsville, New Jersey 08070.

Dated at Rockville, Maryland, this 7th day of June, 1990.

For the Nuclear Regulatory Commission.

Walter R. Butler,

Director, Project Directorate I–2, Division of Reactor Projects I/II, Office of Nuclear Reactor Regulation.

[FR Doc. 90–14231 Filed 6–19–90; 8:45 am]

BILLING CODE 7590–01–M

Advisory Committee on Reactor Safeguards Subcommittee on Improved Light Water Reactors; Meeting

The Subcommittee on Improved Light Water Reactors will hold a meeting on July 11, 1990, room P–110, 7920 Norfolk Avenue, Bethesda, MD.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, July 11, 1990—8:30 a.m. Until the Conclusion of Business

The Subcommittee will review the draft SER for Chapter 5 of the EPRI ALWR Requirements Documents.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Recordings will be permitted only during those portions of the meeting open to the public, and questions may be asked only by members of the Subcommittee, its consultants, and staff. Persons desiring to make oral statements should notify the ACRS staff member named below as far in advance as is practicable so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC staff and EPRI regarding this review.

Further information regarding topics to be discussed, the scheduling of sessions open to the public, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant ACRS staff member, Mr. Medhat El-Zeftawy (telephone 301/492–9901) between 7:30 a.m. and 4:15 p.m. Persons planning to attend this meeting are urged to contact the above named individual one or two days before the scheduled meeting to be advised of any changes in schedule, etc., which may have occurred.

Dated: June 13, 1990.

Gary R. Quittschreiber,

Chief, Nuclear Reactors Branch.

[FR Doc. 90–14233 Filed 6–19–90; 8:45 am]

BILLING CODE 7590–01–M

Advisory Committee on Reactor Safeguards (ACRS) and Advisory Committee on Nuclear Waste (ACNW); Proposed Meetings

In order to provide advance information regarding proposed public meetings of the ACRS Subcommittees and meetings of the ACRS full Committee, and of the ACNW, the following preliminary schedule is published to reflect the current situation, taking into account additional meetings which have been scheduled and meetings which have been postponed or cancelled since the last list of proposed meetings published May 22, 1990 (55 FR 21126). Those meetings which are definitely scheduled have had, or will have, an individual notice published in the **Federal Register** approximately 15 days (or more) prior to the meeting. It is expected that sessions of ACRS full Committee and ACNW meetings designated by an asterisk (*) will be open in whole or in part to the public. ACRS full Committee and ACNW meetings begin at 8:30 a.m. and ACRS Subcommittee meetings usually begin at

8:30 a.m. The time when items listed on the agenda will be discussed during ACRS full Committee and ACNW meetings and when ACRS Subcommittee meetings will start will be published prior to each meeting. Information as to whether a meeting has been firmly scheduled, cancelled, or rescheduled, or whether changes have been made in the agenda for the July 1990 ACRS and ACNW full Committee meetings can be obtained by a prepaid telephone call to the Office of the Executive Director of the Committees (telephone: 301/492–4600 (recording) or 301/492–7288, Attn: Barbara Jo White) between 7:30 a.m. and 4:15 p.m., Eastern Time.

ACRS Committee Meetings

Improved Light-Water Reactors, July 11, 1990, Bethesda, MD. The Subcommittee will review the draft SER for Chapter 5 of the EPRI ALWR Requirements Document.

Improved Light-Water Reactors, July 30, 1990, Bethesda, MD. The Subcommittee will review the NRC staff's proposal for the completeness of designs of the Evolutionary Light-Water Reactors and the Passive Plants.

Human Factors, July 31, 1990, Bethesda, MD. The Subcommittee will discuss the reports on procedural violations (Chernobyl Spin-off), and organizational factors.

Occupational and Environmental Protection Systems, August 8, 1990 (tentative), Bethesda, MD. The Subcommittee will review the Advance Notice of Proposed Rulemaking on hot particles.

Joint Advanced Pressurized Water Reactors and Advanced Boiling Water Reactors, Date to be determined (late July), Bethesda, MD. The Subcommittees will discuss the licensing review basis documents for CE System 80+ and GE ABWR designs.

Decay Heat Removal Systems, Date to be determined (August), Bethesda, MD. The Subcommittee will continue its review of the proposed resolution of Generic Issue 23, "RCP Seal Failures."

Thermal Hydraulic Phenomena, Date to be determined (August), Idaho Falls, ID. The Subcommittee will review the details of the modifications made to the RELAP–5 MOD–2 code as specified in the MOD–3 version.

Joint Severe Accidents and Probabilistic Risk Assessment, Date to be determined (August/September), Bethesda, MD. The Subcommittees will continue their review of NUREG–1150, "Severe Accident Risks: An Assessment for Five U.S. Nuclear Power Plants.

Joint Containment Systems and Structural Engineering, Date to be determined (August/September), Bethesda, MD. The Subcommittees will develop containment design criteria for future plants.

TVA Plant Licensing and Restart, Date to be determined (August/September), Huntsville, AL. The Subcommittee will review the planned restart of Browns Ferry Unit 2.

Materials and Metallurgy, Date to be determined, Bethesda, MD. The Subcommittee will review the proposed resolution of Generic Issue 29, "Bolting Degradation or Failure in Nuclear Power Plants."

Quality and Quality Assurance in Design and Construction, Date to be determined, Bethesda, MD. The Subcommittee will discuss the performance-based concept of quality, what it means, its implementation, and preliminary results.

Decay Heat Removal Systems, Date to be determined, Bethesda, MD. The Subcommittee will explore the use of feed and bleed for decay heat removal in PWRs.

Auxiliary and Secondary Systems, Date to be determined, Bethsda, MD. The Subcommittee will discuss: (1) Criteria being used by utilities to design Chilled Water Systems, (2) regulatory requirements for Chilled Water Systems design, and (3) criteria being used by the NRC staff to review the Chilled Water Systems design.

Joint Regulatory Activities and Containment Systems, Date to be determined, Bethesda, MD. The Subcommittees will review the proposed final revision to Appendix J to 10 CFR Part 50, "Primary Reactor Containment Leakage Testing for Water-Cooled Power Reactors," and an associated Regulatory Guide.

ACRS Full Committee Meetings

363rd ACRS Meeting, July 12–14, 1990, Bethesda, MD. Items are tentatively scheduled.

* A. *Nuclear Power Plant Operating Experience (Open/Closed)*—Briefing and discussion of U.S. and foreign nuclear power plant operating experience including transients and incidents. Specific items that will be addressed include cracking of primary system pressurizers and reactor pressure vessel heads, technical details surrounding the $75,000 fine imposed on the Farley Nuclear Plant, and a proposal for changes in the frequency of turbine stop valve testing in Westinghouse nuclear plants. (Portions of this session will be closed as necessary to discuss Proprietary Information and information provided in confidence by a foreign source).

* B. *Emergency Operating Procedures (Open)*—Briefing by representatives of the NRC staff and the nuclear industry as appropriate regarding NRC efforts related to the development of emergency operating procedures and performance of PRAs for the shut-down modes of operation.

* C. *Systematic Assessment of Licensee Performance Evaluation (Open)*—Briefing by and discussion with members of the NRC staff regarding its evaluation of the SALP system. ACRS comments will be developed as appropriate.

* D. *EPRI Advanced LWR Requirements Document (Open)*—Review and report on the NRC staff's draft SER on chapter 5 of the EPRI Requirements document. Representatives of the NRC staff and EPRI will participate as appropriate.

* E. *ACRS Subcommittee Activities (Open)*—Hear and discuss reports of the status of ACRS subcommittee activities regarding assignments in designated areas such as thermal-hydraulic phenomena, reliability of nuclear power plant fire dampers and related matters.

* F. *Anticipated ACRS Activities (Open)*—Discuss anticipated ACRS subcommittee activities and items proposed for consideration of the full Committee. Procedures for conduct of subcommittee and working-group (subgroup) meetings will also be discussed.

G. *NRC Personnel Action (Closed)*—Discussed status of NRC personnel action. (This session will be closed to discuss information the release of which would represent a clearly unwarranted invasion of personal privacy and internal NRC personnel rules and practices).

* H. *Preparation of ACRS Reports/Comments (Open)*—The Committee will discuss proposed reports to the NRC as appropirate.

364th ACRS Meeting, August 9–11, 1990—Agenda to be announced.

365th Meeting, September 6–8, 1990—Agenda to be announced.

ACNW Full Committee Meetings

21st ACNW Meeting, June 28–29, 1990, Bethesda, MD. Items are tentatively scheduled.

* A. The Committee will discuss past ACNW accomplishments and the future direction of the Committee such as procedures for setting priorities for review topics and Committee interaction with the NRC staff and other organizations.

* B. Briefing on the technology involved in the use of tunnel boring machines and drill and blast excavation techniques.

* C. Briefing on the findings of the recent BEIR V report, "Health Effects of Exposure to Low Levels of Ionizing Radiation."

* D. Briefing on a methodology for predicting the I-129 source term for low level waste sites.

* E. Briefing on transportation and storage of spent nuclear fuel—experience at Morris, Illinois, offsite spent fuel storage facility.

* F. The Committee will discuss and prepare proposed reports to the NRC as appropriate.

* G. The Committee will discuss anticipated and proposed Committee activities, future meeting agenda, and organizational matters, as appropriate.

22nd ACNW Meeting, July 30–31, 1990, Bethesda, MD. Items are tentatively scheduled.

* A. Briefing on Pathfinder Atomic Power Plant dismantlement—The Committee will be briefed on the NRC staff's findings in their safety evaluation report.

* B. Briefing on the status of proactive work (technical positions and rules) in the Division of HLWM and the impact of changes in DOE program and schedule on HLW program.

* C. Briefing on recent trips to review radioactive waste management activities in the U.S.S.R.

* D. Briefing on the status of the QA activities associated with the HLW repository.

23rd ACNW Meeting, August 29–31, 1990—Agenda to be announced.

24th ACNW Meeting, September 27–28, 1990—Agenda to be announced.

Dated: June 14, 1990.

John C. Hoyle,

Advisory Committee Management Officer.

[FR Doc. 90-14234 Filed 6-19-90; 8:45 am]

BILLING CODE 7590-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34-28123; File No. SR-DTC-89-21]

Self-Regulatory Organizations; Order Approving Proposed Rule Change by Depository Trust Company Relating to a Participant Exchange Service Which Will Permit the Transmission of Various Notices on the Participant Terminal System

The Depository Trust Company ("DTC"), on November 27, 1989, filed a proposed rule change (File No. SR-DTC-89-21) with the Securities and Exchange Commission ("Commission") under section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1). Notice of the proposal was published in the **Federal Register** on April 18, 1990.[1] No comments were received. This order approves the proposal.

I. Description of the Proposal

The proposed rule change authorizes DTC to provide its participants with the Participant Exchange Service ("PEX"), an on-line electronic communications network developed by DTC to deal with buy-in notices. PEX will enable DTC participants to use their existing Participant Terminal System ("PTS") terminals to send and respond to National Association of Securities Dealers ("NASD") and National Securities Clearing Corporation ("NSCC") buy-in notices. Specifically, the proposal would permit: (1) Automated completion of the paper forms required by NASD and NSCC, and (2) transmission of the forms by electronic means rather than by physical delivery.

II. Rationale of the Proposal

The purpose of the proposal is to automate the use of buy-in notices by replacing the paper forms currently in use with automated message procedures and by replacing physical delivery with electronic communications. DTC states that the proposal is consistent with section 17A of the Act because it will increase efficiency in connection with the processing of securities transactions.

III. Discussion

The Commission believes that the rule change is consistent with the Act. Section 17A(a)(1) of the Act states that inefficient procedures for the clearance and settlement of securities transactions impose unnecessary costs on investors and on persons facilitating transactions on behalf of investors. Additionally, that provision of the Act expressly encourages the use of automation to improve efficiency in the clearing, settling, and processing of information with respect to securities transactions.[2] Moreover, section 17A(b)(3)(F) of the Act states that clearing agency rules should provide for the prompt and efficient processing of securities transactions.

The Commission notes that, under current NSCC practice, buy-in notices require the completion of paper forms and physical delivery by mail or messenger. This proposal, by providing for the automated transmission of buy-in notices, clearly offers substantial improvements over the existing manually intensive procedures. The Commission believes that using modern technology to make the buy-in process more efficient is fully consistent with the language of the Act, particularly section 17A of the Act.[3]

In addition, this proposal will not affect the safeguarding of funds or securities in DTC's possession or control because DTC is not assuming any additional liabilities in connection with its PEX services. DTC specifically is disclaiming any liability for errors in the content or transmission of buy-in notices and will advise its participants of that disclaimer when the service is implemented.[4]

IV. Conclusion

For the reasons discussed in this order, the Commission finds that the proposal is consistent with the requirements of the Act, particularly section 17A of the Act and the rules and regulations thereunder.

It is therefore ordered, pursuant to section 19(b)(2) of the Act, that the above-mentioned proposed rule change (File No. SR-DTC-89-21) be, and hereby is, approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority (17 CFR 200.30-3(a)(12)).

Dated: June 13, 1990.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 90-14246 Filed 6-19-90; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-28117; File No. SR-PHLX-89-58]

Self-Regulatory Organizations; Philadelphia Stock Exchange, Inc.; Order Approving Proposed Rule Change Relating to the Execution of Foreign Currency Options and Futures Multi-Part Orders

On December 12, 1939, the Philadelphia Stock Exchange, Inc., ("PHLX" or "Exchange") submitted to the Securities and Exchange Commission ("Commission"), pursuant to section 19(b)(1) of the Securities

[1] *See* Securities Exchange Act Release No. 27885, April 10, 1900), 55 FR 14538.

[2] *See also*, Senate Banking, Housing and Urban Affairs Comm., *Report to Accompany S. 249: Securities Acts Amendments of 1975*, S. Rep. No. 75, 94th Cong., 1st Sess. 27–28, 96 (1975).

[3] DTC also has represented in a letter to the Commission that PEX has adequate capacity for its anticipated message traffic and that PEX operations will impose no strain on DTC's data processing capacity. *See* letter from Karen C. Lind, Associate Counsel, DTC, to Thomas C. Etter, Attorney, SEC, dated March 15, 1990.

[4] *See* letter from Karen C. Lind, Associate Counsel, DTC, to Thomas C. Etter, Attorney, SEC, dated March 15, 1990.

Exchange Act of 1934 ("Act") [1] and Rule 19b–4 thereunder,[2] a proposed rule change to amend its rules regarding the execution of foreign currency options and futures multi-part orders.

The proposed rule change was published in Securities Exchange Act Release No. 27597 (January 9, 1990), 55 FR 1759. No comments were received on the proposed rule change.

The Exchange proposes to amend its Rule 1068 relating to the execution of foreign currency options and futures multi-part orders.[3] The Exchange's options trading floor and the Philadelphia Board of Trade ("PBOT") trading floor are contiguous for each foreign currency that is traded on the Exchange. Currently, an Exchange member that desires to effect a multi-part foreign currency trade is required to query the options and futures markets before requesting bids and offers for the multi-part order.[4] Specifically, a member first must request from the options trading crowd a market regarding the options leg of the transaction. Next, the member must request a market for the futures leg of the transaction from the futures trading crowd, and then announce a price between the bid and offer that the member is willing to execute the futures leg of the order. Then the member must provide an opportunity for bids and offers in the options to be made. After soliciting the trading crowds, a multi-part order can only be executed if it is within the current quotations in the options and futures markets (or satisfies all interest at the options bid or offer).[5]

The PJLX proposal would permit a trader to seek execution of a multi-part order without first querying the market as previously provided. Specifically, the proposal provides that a member that desires to initiate a multi-part order shall ascertain from the participants in both the options and futures trading crowd the best price at which a specific amount of options contracts could be bought (or sold) concomitantly with the sale or purchase of a stated amount of futures at a given price.[6] Subsequently the member may execute the multi-part order, provided that the options leg of the multi-part order is better than the individual option quote and the futures leg of the multi-part order is also better than the individual futures quote.

The PHLX proposal also provides members with the opportunity to cross a multi-part order provided a reasonable amount of time is allowed for those in the trading crowd, including the Board Broker, to accept the terms to the multi-part order before crossing such order.[7] The presence of the specialist in the options market and the Board Broker in the futures market ensures that public customer orders placed on the limit order book are not bypassed by multi-part orders and that orders are in fact executed between the best bid and offer.[8]

Multi-part orders with offsetting options and futures components provide investors, in essence, with the opportunity to execute a hedged foreign currency position at a single net price. Under the PHLX proposal, multi-part orders however, would not be bid or offered on a net basis; thus permitting all orders, including booked orders, to participate in multi-part bids and offers.

The Exchange believes that the proposed rule will allow multi-part orders to be executed more efficiently. The proposed rule, by eliminating the querying of the markets for the individual legs of the order, should reduce the execution time for multi-part orders and this may be critical for investors in volatile currency markets. Accordingly, the PHLX believes that the proposed rule allows the Exchange to respond more effectively to the competitive requirements of the foreign currency futures and options markets by providing for more ready execution of multi-part orders.

The Commission finds that the proposed rule change is consistent with the requirements of the Act and the rules and regulations thereunder applicable to a national securities exchange, and, in particular, the requirements of section 6. Specifically, the Commission finds that the proposed rule changes is consistent with section 6(b)(5) in that it will perfect the mechanism of a free and open market by enabling multi-part orders for foreign currency orders to be more efficiently executed. The foreign currency market is primarily an institutional market with customers and participants often seeking to execute futures and options orders simultaneously as part of their investment strategy.[9] The Commission believes that facilitating the execution of inter-market foreign currency orders will further contribute to a deep and liquid foreign currency options market. Moreover, as with the currrent rule, before a member can execute a multi-part order, the member must offer the order competitively and better the existing options market.[10] Finally, if a market participant also has an opposing match to a multi-part order, the proposal provides reasonable procedures for crossing the orders while ensuring that the crossed orders are exposed to the options crowd.[11]

In sum, the Commission believes that facilitating the execution of inter-regulatory multi-part orders allows investors to engage more readily in sophisticated currency transaction in the options and futures markets, thereby

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[1] 15 U.S.C. 78s(b)(1) (1982).

[2] 17 CFR 240.19b–4 (1989).

[3] The Exchange defines a "multi-part order" as an order to buy and/or sell a stated number of foreign currency option contracts and a stated number of foreign currency futures contracts. PHLX Rule 1066(c). An example of a multi-part order is an order to buy 100 contracts of Japanese Yen ("JY") September ("SEP") calls with a strike price of 72 in combination with an order to sell 25 JY SEP futures contracts.

[4] Market participants who are both PHLX and PBOT members may bid or offer for the entire multi-part order, or bid or offer for just one leg of the order. Additionally, PHLX members that are not PBOT members may bid or offer for only the options portion of the order. Currently, there are no PBOT members who are not also PHLX members.

[5] For example, the options portion of the multi-part order, described *supra* in note 3, is comprised of 100 JY SEP long call contracts with a strike price of 72. If the market quotation for such options contracts is bid 3—ask 3½; then the options leg of the multi-part order would have to be executed at a price less than 3½, *i.e.*, 3¼. Similarly, the futures portion of the multi-part order would have to be executed at a price better than the current quotation for the specified futures contract.

[6] For example, under the PHLX proposal a member would request bids to buy 100 JY 72 class in conjunction with an order to sell 25 JY SEP futures contracts at .7118. If the market for JY SEP 72 calls without including the futures leg as part of a multi-part order could only be executed if the options leg is executed at a price less than 3½.

[7] The PHLX amended its proposal to clarify that the Board Broker would be included in the futures trading crowd participants that would receive a reasonable amount of time before a party could cross a multi-part order. *See* letter from Murray Ross, Secretary, PHLX, to Mark McNair, Staff Attorney, SEC, dated March 14, 1990.

[8] There generally are few orders on the limit order book for foreign currency derivative transactions. On the PBOT, the Board Broker, among other things, is responsible for (1) maintaining the book; (2) effecting the proper execution of such orders; and (3) monitoring the markets assigned to him. *See* PBOT Rule 331.

[9] The Commission, in response to another proposal that reflects the institutional nature of the foreign currency markets, has approved a PHLX proposal to permit three-way orders of foreign currency options to be executed with one market participant at a total credit or debit. *See* Securities Exchange Act Release No. 27730 (February 23, 1990), 55 FR 7616.

[10] The Commission believes that the PHLX proposal is consistent with rules of the Chicago Board Options Exchange and Chicago Board of Trade pertaining to the execution of certain inter-regulatory spread orders between the Standard and Poor's 500 Index option and certain stock index futures orders. *See* Securities Exchange Act Release No. 26271 (November 10, 1988), 53 FR 46727.

[11] As previously noted, this is done in a framework that ensures that orders are executed at prices better than the prevailing market and protects public customer orders placed on the book.

contributing to the maintenance of a free and open market and enhancing liquidity.[12]

It is therefore ordered, pursuant to section 19(b)(2) of the Act, [13] that the proposed rule change (SR–PHLX–89–58) is approved.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[14]

Dated: June 14, 1990.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 90–14245 Filed 6–19–90; am]

BILLING CODE 8010–01–M

[File No. 22–20047]

Application and Opportunity for Hearing; Shell Oil Co.

June 15, 1990.

Notice is hereby given that Shell Oil Company (the "Company") has filed an application pursuant to section 310(b)(1)(ii) of the Trust Indenture Act of 1939, as amended (the "Act"), for a finding by the Securities and Exchange Commission (the "Commission") that the trusteeship of The Bank of New York ("BNY") under one indenture which is qualified under the Act and five indentures not so qualified, and under another indenture which is qualified under the Act pursuant to which BNY is the successor in the merger between Irving Trust Company and old The Bank of New York ("Old BNY"), is not so likely to involve a material conflict of interest as to make it necessary in the public interest or for the protection of investors to disqualify BNY from acting as Trustee under any of said indentures.

Section 310(b) of the Act provides in part that if a trustee under an indenture qualified under the Act has or shall acquire any conflicting interest (as defined in the section), it shall, within ninety days after ascertaining that it has such conflicting interest, either eliminate such conflicting interest or resign. Subsection (1) of that section provides, with certain exceptions stated therein, that a trustee under a qualified indenture shall be deemed to have a conflicting interest if such trustee is trustee under another indenture of the same obligor.

The Company alleges that:

1. (a) BNY, as Trustee, entered into two indentures dated March 15, 1966 (the "1966 Indenture") and March 15, 1967 (the "1967 Indenture") with the Company pursuant to which there were issued $150,000,000 aggregate principal amount of the Company's 5% Debentures due 1991 (the "1966 Debentures") and $150,000,000 aggregate principal amount of the Company's 5.30% Debentures due 1992 (the "1967 Debentures"), respectively. The 1967 Indenture was filed as Exhibit 2(a) to the Registration Statement No. 2–26028 under the Securities Act of 1933, as amended (the "1933 Act") and has been qualified under the Act. The 1966 Indenture was not qualified under the Act on the basis of the provision in section 304(b) of the Act relating to securities sold without registration in reliance on section 4 of the 1933 Act.

(b) On May 19, 1982, the Industrial Pollution Control Financing Authority of Middlesex County, a public body politic and corporate and a political subdivision of the State of New Jersey (the "Authority") and BNY, as Trustee, entered into an indenture dated as of May 1, 1982 (the "1982 Indenture") pursuant to which the Authority issued its Pollution Control Revenue Bonds Series 1982 (Shell Oil Company Project) in the aggregate principal amount of $6,000,000 (the "1982 Bonds"). The 1982 Bonds were issued to finance the cost of certain pollution control facilities at the Company's marketing distribution plant located in Middlesex County, New Jersey. The Authority entered into an Agreement of Sale dated as of May 1, 1982 with the Company (the "1982 Agreement of Sale") pursuant to which said facilities were, upon completion thereof from time to time, acquired by the Authority and simultaneously resold to the Company. The 1982 Bonds are payable from, and are secured by a pledge of, the income and revenue derived from the sale of said facilities, which income and revenues will be sufficient to pay the principal of and interest on the 1982 Bonds. The 1982 Bonds were not registered under the 1933 Act on the basis of the exemption provided by section 3(a)(2) thereof and the 1982 Indenture was not qualified under the Act on the basis of the provisions of secton 304(a)(4)(A) thereof. In addition, the Parish of St. Charles, a political subdivision of the State of Louisiana (the "Parish"), and BNY, as Trustee, entered into an indenture dated as of May 1, 1985 (the "1985 Indenture") pursuant to which the Parish issued its Parish of St. Charles, State of Louisiana, 7 & 7 Pollution Control Revenue Refunding Bonds (Shell Oil Company Project), Series 1985, in the aggregate principal amount of $15,000,000 (the "1985 Bonds"). The 1985 Bonds were issued to refund the cost of certain pollution control facilties at the Company's chemical plant located in the Parish. The Parish entered into a Sale Agreement dated as of May 1, 1985 with the Company (the "1985 Sale Agreement") pursuant to which said facilities were, upon completion thereof from time to time, acquired by the Parish and simultaneously resold to the Company. The 1985 Bonds are payable from, and are secured by a pledge of, the income and revenues derived from the sale of said facilities, which income and revenues will be sufficient to pay the principal of and the redemption premium (if any) and interest on the 1985 Bonds. The 1985 Bonds were not registered under the 1933 Act on the basis of the exemption provided by section 3(a)(2) thereof and the 1985 Indenture was not qualified under the Act on the basis of the provisions of section 304(a)(4)(A) thereof.

(c) Bankers Trust Company, a New York corporation ("Bankers Trust") and BNY, as Trustee, entered into two Indentures and First Preferred Ship Mortgages dated as of March 14, 1978 and October 25, 1978 (respectively, the "B.T. Alaska Indenture" and the "B.T. San Diego Indenture") pursuant to which Bankers Trust issued three series of 8.40% Secured Ship Financing Notes, Series A consisting of an aggregate principal amount of $40,595,905, Series B consisting of an aggregate principal amount of $13,000,000 and Series C consisting of an aggregate principal amount of $3,674,875, and $55,725,233 aggregate principal amount of 9.125% Secured Ship Financing Notes (respectively, the "B.T. Alaska Notes" and the "B.T. San Diego Notes"). The B.T. Alaska Notes and the B.T. San Diego Notes were issued to finance the cost of the B.T. Alaska and the B.T. San Diego, each a San Diego class oil tanker. Bankers Trust entered into two Demise Charters with Marine Alaska, Inc. ("Marine Alaska"), and Marine San Diego, Inc. ("Marine San Diego"), both Delaware corporations, pursuant to which Bankers Trust chartered the B.T. Alaska and the B.T. San Diego to, respectively, Marine Alaska and Marine San Diego. Marine Alaska and Marine San Diego in turn entered into two Time Charters with the Company, pursuant to which Marine Alaska and Marine San Diego respectively chartered the B.T. Alaska and the B.T. San Diego to the

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[12] The PHLX and the Commission has discussed the proposal with the staff of the Commodity Futures Trading Commission ("CFTC"), and the CFTC staff does not have any objections to this proposal by the PHLX to amend its rules regarding the execution of foreign currency options and futures multi-part orders. Discussion between Shauna Turnbull, Staff Attorney, CFTC, and Mark McNair, Staff Attorney, SEC, June 1, 1990. Moreover, PBOT plans to submit a corresponding proposal to the CFTC.

[13] 15 U.S.C. 78s(b)(2).

[14] 17 CFR 200.30–2(a)(12) (1989).

Company. The Time Charters were assigned to Bankers Trust by each of Marine Alaska and Marine San Diego. In addition, the obligations of each of Marine Alaska and Marine San Diego to Bankers Trust under their respective Demise Charters were guaranteed by the Company pursuant to two Guaranty Agreements (the "Guaranties") entered into between the Company and Bankers Trust. The B.T. Alaska Notes and the B.T. San Diego Notes are payable from and are secured by, among other things, their respective Demise Charters, Time Charters and Guaranties, and, respectively, the B.T. Alaska and the B.T. San Diego. The B.T. Alaska Notes and the B.T. San Diego Notes were not registered under the 1933 Act on the basis of the exemption provided by section 3(a)(2) thereof and the B.T. Alaska Indenture and B.T. San Diego Indenture were not qualified under the Act on the basis of the provisions of the section 304(a)(4)(A) thereof.

2. Old BNY, as Trustee, entered into a Standard Multi-Series Indenture dated December 16, 1985 (the "Multi-Series Indenture") with the Company pursuant to which there were issued, under five supplemental indentures, $25,000,000 aggregate principal amount of the Company's 1986 First Series Medium Term Notes, $250,000,000 aggregate principal amount of the Company's 8⅜% Notes due 1996, $250,000,000 aggregate principal amount of the Company's 7¼% Notes due 1991 and $500,000,000 aggregate principal amount of the Company's 1988 First Series Medium Term Notes (collectively, the "Multi-Series Notes"). The Multi-Series Indenture was filed as Exhibit 4(a) to the post-effective Amendment No. 1 to the Registration Statement No. 2–79919 under the 1933 Act and has been qualified under the Act.

3. Only July 23, 1985, the Commission, upon application by the Company and due notice and opportunity for a hearing on said application, entered an order finding that the trusteeships of BNY under the 1966 Indenture, the 1967 Indenture, the 1982 Indenture and the 1985 Indenture were not so likely to involve a material conflict of interest as to make it necessary in the public interest or for the protection of investors to disqualify BNY from acting as Trustee under any of said Indentures.

4. Under § 7.08(c)(1)(ii) of the Multi-Series Indenture, § 6.08(c)(1)(ii) of the 1966 Indenture and § 8.08(c)(1)(ii) of the 1967 Indenture, BNY shall not be deemed to have a conflicting interest by reasons of acting as Trustee under the Multi-Series Indenture, the 1966 Indenture, the 1967 Indenture, the 1982 Indenture, the 1985 Indenture, the B.T. Alaska Indenture and the B.T. San Diego Indenture if the Company shall have sustained the burden of proving, on application to the Commission and after opportunity for hearing thereon, that the tursteeships of BNY under the Multi-Series Indenture, the 1966 Indenture, the 1967 Indenture, the 1982 Indenture, the 1985 Indenture, the B.T. Alaska Indenture and the B.T. San Diego Indenture are not so likely to involve a material conflict of interest as to make it necessary in the public interest or for the protection of investors to disqualify BNY from acting as Trustee under any of said Indenture.

5. The Company is not in default under the Multi-Series Indenture, the 1966 Indenture, the 1967 Indenture, the 1982 Agreement of Sale, the 1985 Sale Agreement, the Time Charters or the Guaranties. The Company's obligations under the Multi-Series Indenture, the 1966 Indenture, the 1967 Indenture, and its obligations under the 1982 Agreement of Sale, the 1985 Sale Agreement, the Time Charters and the Guaranties as they relate to the Multi-Series Notes, the 1966 Debentures, the 1967 Debentures, the 1982 Bonds, the 1985 Bonds, the B.T. Alaska Notes and the B.T. San Diego Notes are wholly unsecured and rank equally *pari passu*.

6. The provisions of the Multi-Series Indenture, the 1966 Indenture, the 1967 Indenture, the 1982 Indenture, the 1982 Agreement of Sale, the 1985 Indenture, the 1985 Sale Agreement, the B.T. Alaska Indenture, the B.T. San Diego Indenture, the Time Charters and the Guaranties are not so likely to involve a materials conflict of interest as to make it necessary in the public interest or for the protection of investors to disqualify BNY from acting as Trustee under any of said Indentures.

The Company has waived notice of hearing, any right to a hearing on the issues raised by the Application and all rights to specify procedures under Rule 8(b) of the Rules of Practice of the Commission with respect to this Application.

For a more detailed account of the matters of fact and law asserted, all persons are referred to said application, which is a public document on file in the Offices of the Commission's Public Reference Section, File Number 22–20047, 450 Fifth Street, NW., room 1024, Washington, DC 20549.

Notice is further given that any interested person may, not later than July 10, 1990 request in writing that a hearing be held on such matter, stating the nature of his interest, the reasons for such request, and the issues of law or fact raised by such application which he desires to controvert, or he may request that he be notified if the Commission should order a hearing thereon. Any such request should be addressed: Secretary, Securities and Exchange Commission, Washington, DC 20549. At any time after said date, the Commission may issue an order granting the application upon such terms and conditions as the Commission may deem necessary or appropriate in the public interest and for the protection of investors, unless a hearing is ordered by the Commission.

For the Commission, by the Division of Corporation Finance, pursuant to delegated authority.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 90–14243 Filed 6–19–90; 8:45 am]

BILLING CODE 8010–01–M

[Rel. No. IC–17530; 812–7533]

Application; the Singapore Fund, Inc.

June 13, 1990.

AGENCY: Securities and Exchange Commission ("SEC").

ACTION: Notice of application for exemption under the Investment Company of 1940 ("Act").

APPLICANT: The Singapore Fund, Inc.

RELEVANT ACT SECTIONS: Exemption requested under section 6(c) from the provisions of section 12(d)(3) and Rule 12d3–1.

SUMMARY OF APPLICATION: Applicant seeks a conditional order permitting it to invest in equity and convertible debt securities of foreign issuers that, in each of their most recent fiscal years, derived more than 15% of their gross revenues from their activities as a broker, dealer, underwriter or investment adviser ("foreign securities companies") in accordance with the conditions of the proposed amendments to Rule 12d3–1.

FILING DATE: The application was filed on June 8, 1990.

HEARING OR NOTIFICATION OF HEARING: An order granting the application will be issued unless the SEC orders a hearing. Interested persons may request a hearing by writing to the SEC's Secretary and serving applicant with a copy of the request, personally or by mail. Hearing requests should be received by the SEC by 5:30 p.m. on July 10, 1990, and should be accompanied by proof of service on the applicant, in the form of an affidavit or, for lawyers, a certificate of service. Hearing requests should state the nature of the writer's

interest, the reason for the request, the the issues contested. Persons may request notification of a hearing by writing to the SEC's Secretary.

ADDRESSES: Secretary, SEC, 450 5th Street NW., Washington, DC 20549. Applicant, 200 Liberty Street, New York, NY 10281.

FOR FURTHER INFORMATION CONTACT: Jeremy N. Rubenstein, Branch Chief, at (202) 272–3023 (Division of Investment Management, Office of Investment Company Regulation).

SUPPLEMENTARY INFORMATION: The following is a summary of the application. The complete application may be obtained for a fee at the SEC's Public Reference Branch or by contacting the SEC's commercial copier at (800) 231–3282 (in Maryland (301) 258–4300).

Applicant's Representations

1. Applicant is a Maryland corporation and is a closed-end management investment company registered under the Act. On June 1, 1990, applicant filed a notification of registration on Form N–8A under the Act and a registration statement on Form N–2 under the Act and the Securities Act of 1933. Applicant's investment manager is DBS Asset Management (United States) Pte. Ltd., a company organized under the laws of the Republic of Singapore, which is a wholly-owned subsidiary of DBS Asset Management Limited, itself a wholly-owned subsidiary of The Development Bank of Singapore, Ltd. Applicant's investment adviser, Daiwa International Capital Management (Singapore) Ltd., is a company organized under the laws of the Republic of Singapore and is a subsidiary of Daiwa International Capital Management Co., Ltd.

2. Applicant seeks to diversify its portfolio further by being permitted to invest in Singapore and other foreign issuers that, in their most recent fiscal year, derived more than 15% of their gross revenues from their activities as a broker, dealer, underwriter, or investment adviser.

3. Applicant seeks relief from section 12(d)(3) of the Act and Rule 12d3–1 thereunder to invest in securities of foreign securities companies to the extent allowed in the proposed amendments to Rule 12d3–1. *See* Investment Company Act Release No. 17096 (Aug. 3, 1989), 54 FR 33027 (Aug. 11, 1989). Proposed amended Rule 12d3–1 would, among other things, facilitate the acquisition by applicant of equity securities issued by foreign securities companies. Applicant's proposed acquisitions of securities issued by foreign securities companies will satisfy each of the requirements of proposed amended Rule 12d3–1.

Applicant's Legal Conclusions

1. Section 12(d)(3) of the Act prohibits an investment company from acquiring any security issued by any person who is a broker, dealer, underwriter, or investment adviser. Rule 12d3–1 under the Act provides an exemption from section 12(d)(3) for investment companies acquiring securities of an issuer that derived more than 15% of its gross revenues in its most recent fiscal year from securities-related activities, provided the acquisitions satisfy certain conditions set forth in the rule. Subparagraph (b)(4) of Rule 12d3–1 provides that "any equity security of the issuer * * * [must be] a 'margin security' as defined in Regulation T promulgated by the Board of Governors of the Federal Reserve System." Since a "margin security" generally must be one which is traded in the United States markets, securities issued by many foreign securities firms would not meet this test. Accordingly, Applicant seeks an exemption from the "margin security" requirements of Rule 12d3–1.

2. Proposed amended Rule 12d3–1 provides that the "margin security" requirement would be excused if the acquiring company purchases the equity securities of foreign securities companies that meet criteria comparable to those applicable to equity securities of United States securities-related businesses. The criteria, as set forth in the proposed amendments, "are based particularly on the policies that underlie the requirements for inclusion on the list of over-the-counter margin stocks." Investment Company Act Release No. 17096 (Aug. 3, 1989), 54 FR 33027 (Aug. 11, 1989).

Applicant's Condition

Applicant agrees to the following condition in connection with the relief requested:

Applicant will comply with the provisions of the proposed amendments to Rule 12d3–1 (Investment Company Act Release No. 17096 (Aug. 3, 1989); 54 FR 33027 (Aug. 11, 1989)), and as such amendments may be reproposed, adopted, or amended.

For the Commission, by the Division of Investment Management, under delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 90–14244 Filed 6–19–90; 8:45 am]

BILLING CODE 8010–01–M

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster Loan Area #2422]

Declaration of Disaster Loan Area; Arkansas

As a result of the President's major disaster declaration on May 15, 1990, and amendments on May 20, 22, 25, and 29, 1990, I find that the Counties of Benton, Boone, Carroll, Clark, Clay, Columbia, Conway, Crawford, Crawford, Faulkner, Franklin, Garland, Hempstead, Hot Spring, Izard, Jefferson, Lafayette, Little River, Logan, Madison, Marion, Miller, Newton, Perry, Pike, Polk, Pope, Pulaski, Scott, Sebastian, Stone, Union, and Yell in the State of Arkansas constitute a disaster area as a result of damages caused by severe storms and flooding beginning on May 1, 1990. Applications for loans for physical damage may be filed until the close of business on July 14, 1990, and for loans for economic injury until the close of business on February 15, 1991, at the address listed below: Disaster Area 3 Office, Small Business Administration, 4400 Amon Carter Blvd., suite 102, Ft. Worth, TX 76155, or other locally announced locations. In addition, applications for economic injury loans from small business located in the contiguous counties of Arkansas, Ashely, Baxter, Bradley, Calhoun, Cleburne, Cleveland, Dallas, Fulton, Grant, Greene, Howard, Independence, Lincoln, Lonoke, Montgomery, Nevada, Ouachita, Randolph, Saline, Searcy, Sevier, Sharp, Van Buren, Washington, and White, in the State of Arkansas; Delaware County in the State of Oklahoma; Barry, Butler, Dunklin, McDonald, Ozark, Ripley, Stone, and Taney Counties in the State of Missouri; and the parishes of Bossier, Caddo, Claiborne, Morehouse, Union, and Webster, in the State of Louisiana may be filed until the specified date at the above location.

Any counties contiguous to the above-named primary counties and not listed herein have previously been named as contiguous or primary counties for the same occurrence.

The interest rates are:

For Physical Damage:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	8.000
Homeowners Without Credit Available Elsewhere	4.000

	Percent
Businesses With Credit Available Elsewhere	8.000
Businesses and Non-profit Organizations Without Credit Available Elsewhere	4.000
Others (Including Non-profit Organizations) With Credit Available Elsehwere	9.250
For Economic Injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage for the State of Arkansas is 242206. For economic injury the numbers are 706500 for the State of Arkansas; 706400 for the State of Oklahoma; 706600 for the State of Missouri, and 7077 for the State of Louisiana.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: June 5, 1990.

Alfred E. Judd,

Acting Assistant Administrator for Disaster Assistance.

[FR Doc. 90–14221 Filed 6–19–90; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2423]

Declaration of Disaster Loan Area; Hawaii

As a result of the President's major disaster declaration on May 18, 1990, I find that the Island of Hawaii is a disaster area as a result of damages caused by lava flows from the UP' 'O' o and the Kupaianaha Vents of the Kilauea Volcano beginning on January 24, 1983. Applications for loans for physical damage may be filed until such time as determined by the Federal Emergency Management Agency, and applications for loans for economic injury may be filed until the close of business on February 19, 1991, at the address listed below: Disaster Area 4 Office, Small Business Administration, P.O. Box 13795, Sacramento, CA 95853–4795.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	8.000
Homeowners Without Credit Available Elsewhere	4.000
Businesses With Credit Available Elsewhere	8.000
Businesses and Non-profit Organizations Without Credit Available Elsewhere	4.000
Others (Including Non-profit Organizations) With Credit Available Elsewhere	9.250
For Economic Injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage is 242313 and for economic injury the number is 706700.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: June 6, 1990.

Alfred E. Judd,

Acting Assistant Administrator for Disaster Assistance.

[FR Doc. 90–14222 Filed 6–19–90; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2430]

Declaration of Disaster Loan Area; Iowa

As a result of the President's major disaster declaration on May 26, 1990, I find that the counties of Crawford, Plymouth, and Woodbury constitute a disaster area as a result of damages caused by severe storms and flooding beginning on May 18, 1990. Applications for loans for physical damage may be filed until the close of business on July 25, 1990, and for loans for economic injury until the close of business on February 26, 1991, at the address listed below: Disaster Area 3 Office, Small Business Administration, 4400 Amon Carter Blvd., suite 102, Ft. Worth, TX 76155, or other locally announced locations. In addition, applications for economic injury loans from small business located in the contiguous counties of Audubon, Carroll, Cherokee, Harrison, Ida, Monona, O'Brien, Sac, Shelby, and Sioux in the State of Iowa; Dakota and Thurston Counties in the State of Nebraska, and Union County in the State of South Dakota may be filed until the specified date at the above location.

The interest rates are:

	Percent
For physical damage:	
Homeowners with credit available elsewhere	8.000
Homeowners without credit available elsewhere	4.000
Businesses with credit available elsewhere	8.000
Businesses and non-profit organizations without credit available elsewhere	4.000
Others (including non-profit organizations) with credit available elsewhere	9.250
For economic injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	4.000

The number assigned to this disaster for physical damage for the State of Iowa is 243006. For economic injury the numbers are 707400 for the State of Iowa; 707500 for South Dakota; and 707600 for the State of Nebraska.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: June 8, 1990.

Alfred E. Judd,

Acting Assistant Administrator for Disaster Assistance.

[FR Doc. 90–14223 Filed 6–19–90; 8:45 am]

BILLING CODE 8025–01–M

[Declaration of Disaster Loan Area #2429]

Declaration of Disaster Loan Area; Missouri

As a result of the President's major disaster declaration on May 24, 1990, and amendments thereto on May 27 and 31, 1990, I find that Greene, Jackson, and Webster Counties and the City of Kansas City constitute a disaster area as a result of damages caused by severe storms and flooding between May 15 and May 31, 1990. Applications for loans for physical damage may be filed until the close of business on July 23, 1990, and for loans for economic injury until the close of business on February 25, 1991, at the address listed below: Disaster Area 3 Office, Small Business Administration, 4400 Amon Carter Boulevard, Suite 102, Fort Worth, TX 76155, or other locally announced locations. In addition, applications for economic injury loans from small business located in the contiguous counties of Cass, Christian, Clay, Dade, Dallas, Douglas, Greene, Johnson, Laclede, Lafayette, Lawrence, Platte, Polk, Ray, and Wright, in the State of Missouri, and Johnson and Wyandotte Counties in the State of Kansas may be filed until the specified date at the above location.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	8.000
Homeowners Without Credit Available Elsewhere	4.000
Businesses With Credit Available Elsewhere	8.000

	Percent
Businesses and Non-Profit Organizations Without Credit Available Elsewhere	4.000
Others (Including Non-Profit Organizations) With Credit Available Elsewhere	9.250
For Economic Injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000

The number assigned to this disaster for physical damage for the State of Missouri is 242906, and for economic injury the number is 707200. The economic injury number for the State of Kansas is 707300.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: June 6, 1990.

Alfred E. Judd,

Acting Assistant Administrator for Disaster Assistance.

[FR Doc. 90-14224 Filed 6-19-90; 8:45 am]

BILLING CODE 8025-01-M

[Declaration of Disaster Loan Area #2427 and 2428]

Declaration of Disaster Loan Area; Pennsylvania (Contiguous Counties in New Jersey)

Bucks County and the contiguous Counties of Lehigh, Northampton, Montgomery, and Philadelphia in the State of Pennsylvania and Burlington, Hunterdon, and Mercer Counties in the State of New Jersey constitute a disaster area as a result of damages from a fire in the Franklin Commons Apartment Complex, Bensalem Township, Bucks County, Pennsylvania, which occurred May 11, 1990. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on July 30, 1990, and for economic injury applications until the close of business on February 28, 1991, at the address listed below: Disaster Area 2 Office, Small Business Administration, 120 Ralph McGill Boulevard, 14th Floor, Atlanta, GA 30308, or other locally announced locations.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners With Credit Available Elsewhere	8.000
Homeowners Without Credit Available Elsewhere	4.000
Businesses With Credit Available Elsewhere	8.000
Businesses and Non-profit Organizations Without Credit Available Elsewhere	4.000
Others (Including Non-profit Organizations) With Credit Available Elsewhere	9.250
For Economic Injury:	
Businesses and Small Agricultural Cooperatives Without Credit Available Elsewhere	4.000

The number assigned to this disaster for the State of Pennsylvania for physical damage is 242705 and for economic injury the number is 707000. In New Jersey, the physical number is 242805 and the economic injury number is 707100.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008).

Dated: May 30, 1990.

Susan Engeleiter,

Administrator.

[FR Doc. 90-14225 Filed 6-19-90; 8:45 am]

BILLING CODE 8025-01-M

[Declaration of Disaster Loan Area #2421, Amendment #1]

Declaration of Disaster Loan Area, Texas

The above-numbered Declaration is hereby amended in accordance with the amendment to the President's declaration, dated May 7, May 10, May 11, May 16, May 18, and May 19 to include Anderson, Bowie, Clay, Ellis, Fannin, Grayson, Henderson, Hood, Houston, Johnson, Jones, Kaufman, Lamar, Leon, Liberty, Madison, McClennan, Montague, Polk, San Jacinto, Somervell, Taylor, Trinity, Walker, and Young Counties as a result of damages caused by severe storms, tornadoes, and flooding beginning April 15 and continuing.

In addition, applications for economic injury loans from small businesses located in the contiguous Angelina, Archer, Baylor, Bell, Brazos, Cass, Chambers, Cherokee, Delta, Fisher, Franklin, Grimes, Hardin, Harris, Haskell, Hopkins, Jefferson, Montgomery, Morris, Nolan, Red River, Smith, Stonewall, Throckmorton, Tyler, Van Zandt, and Wichita in Texas, in Little River and Miller Counties in Arkansas, and Bryan, Choctaw, Cotton, Jefferson, and McCurtain in Oklahoma may be filed until the specified date at the previously mentioned location. The number assigned for economic injury for the State of Arkansas is 706500. Some of the counties contiguous to the above-named primary counties and listed herein may have previously been named as contiguous or primary counties for the same occurrence.

All other information remains the same, i.e., the termination date for filing applications for physical damage is July 1, 1990, and for economic injury until the close of business on February 4, 1991.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008)

Dated: May 25, 1990.

Alfred E. Judd,

Acting Assistant Administrator for Disaster Assistance.

[FR Doc. 90-14226 Filed 6-19-90; 8:45 am]

BILLING CODE 8025-01-M

Action Subject to Intergovernmental Review

AGENCY: Small Business Administration.

ACTION: Notice of action subject to intergovernmental review under Executive Order 12372.

SUMMARY: This notice provides for public awareness of SBA's intention to refund sixteen presently existent Small Business Development Centers (SBDCs) on October 1, 1990. Currently there are 56 SBDCs operating in the SBDC program. The following SBDCs are intended to be refunded, subject to the availability of funds: Alabama, Alaska, Connecticut, Delaware, Maryland, Mississippi, Missouri, New York (Downstate), Ohio, Puerto Rico, Texas (Dallas), Texas (Lubbock), Texas (San Antonio), Virginia Islands, West Virginia and Wyoming. This notice also provides a description of the SBDC program by setting forth a condensed version of the program announcement which has been furnished to each of the SBDCs to be refunded. This publication is being made to provide the State single points of contact, designated pursuant to Executive Order 12372, and other interested State and local entities, the opportunity to comment on the proposed refunding in accord with the Executive Order and SBA's regulations found at 13 CFR part 135.

EFFECTIVE DATES: September 18, 1990.

ADDRESSES: Comments should be addressed to Ms. Janice E. Wolfe, Associate Administrator for SBDC Program, U.S. Small Business Administration, 1441 L Street NW., Washington, DC 20416.

FOR FURTHER INFORMATION CONTACT: Same as above.

Notice of Action Subject to Intergovernmental Review

SBA is bound by the provisions of Executive Order 12372, "Intergovernmental Review of Federal Programs." SBA has promulgated

regulations spelling out its obligations under that Executive Order. See 13 CFR part 135, effective September 30, 1983.

In accord with these regulations, specifically § 135.4, SBA is publishing this notice to provide public awareness of the pending application of sixteen presently existent Small Business Development Centers (SBDCs) for refunding. Also, published herewith is an annotated program announcement describing the SBDC program in detail.

This notice is being published three months in advance of the expected date of refunding of these SBDCs. Relevant information identifying these SBDC and providing their mailing address is provided below. In addition to this publication, a copy of this notice is being simultaneously furnished to each affected State single point of contact which has been established under the Executive Order.

The State single points of contact and other interested State and local entities are expected to advise the relevant SBDC of their comments regarding the proposed refunding in writing as soon as possible. The SBDC proposal cannot be inconsistent with any area-wide plan providing assistance to small business, if there is one, which has been adopted by an agency recognized by the State government as authorized to do so. Copies of such written comments should also be furnished to Ms. Janice E. Wolfe, Associate Administrator for SBDC Programs, U.S. Small Business Administration, 1441 L Street NW., Washington, DC 20416. Comments will be accepted by the relevant SBDC and SBA for a period of 90 days from the date of publication of this notice. The revelant SBDC will make every effort to accommodate these comments during the 90-day period. If the comments cannot be accommodated by the relevant SBDC, SBA will, prior to refunding the SBDC, either attain accommodation of any comments or furnish an explanation of why accommodation cannot be attained to the commentor prior to refunding the SBDC.

Description of the SBDC Program

The SBDC operates under the general management and oversight of SBA, but with recognition that a partnership exists between the Agency and the SBDC for the delivery of assistance to the small business community. SBDC services shall be provided pursuant to a negotiated Cooperative Agreement with full participation of both parties. SBDCs operate on the basis of a state plan to provide assistance within a state or designated geographic area. The initial plan must have the written approval of the Governor. As a condition to any financial award made to an applicant, non-Federal funds must be provided from sources other than the Federal Government. SBDCs operate under the provisions of Public Law 96–302, as amended by Public Law 98–395, a Notice of Award (Cooperative Agreement) issued by SBA, and the provisions of this Program Announcement.

Purpose and Scope

The SBDC Program is designed to provide quality assistance to small businesses in order to promote growth, expansion, innovation, increased productivity and management improvement. To accomplish these objectives, SBDCs link resources of the Federal, State, and local governments with the resources of the educational system and the private sector to meet the specialized and complex needs to the small business community. SBDCs also coordinates with other SBA programs of business development and utilize the expertise of these affiliated resources to expand services and avoid duplication of effort.

Program Objectives

The overall objective of the SBDC Program is to leverage Federal dollars and resources with those of the state, academic community and private sector to:

(a) Strengthen the small business community;

(b) Contribute to the economic growth of the communities served;

(c) Make assistance available to more small businesses than is now possible with present Federal resources;

(d) Create a broader based delivery system to the small business community.

SBDC Program Organization

SBDCs are organized to provide maximum services to the local small business community. The lead SBDC receives financial assistance from the SBA to operate a statewide SBDC Program. In states where more than one organization receives SBA financial assistance to operate an SBDC, each lead SBDC is responsible for Program operations throughout a specific regional area to be served by the SBDC. The lead SBDC is responsible for establishing a network of SBDC subcenters to offer service coverage to the small business community. The SBDC network is managed and directed by a full-time Director. SBDCs must ensure that at least 80 percent of Federal funds provided are used to provide services to small businesses. To the extent possible, SBDCs provide services to enlisting volunteer and other low cost resources on a statewide basis.

SBDC Services

The specific types of services to be offered are developed in coordination with the SBA district office which has jurisdiction over a given SBDC. SBDCs emphasize the provision of indepth, high-quality assistance to small business owners or prospective small business owners in complex areas that require specialized expertise. These areas may include, but are not limited to: management, marketing, financing, accounting, strategic planning, regulation and taxation, capital formation, procurement assistance, human resource management, production, operations, economic and business data analysis, engineering, technology transfer, innovation and research, new product development, product analysis, plant layout and design, agri-business, computer application, business law information, and referral (any legal services beyond basis legal information and referral require the endorsement of the State Bar Association), exporting, office automation, site selection, or any other areas of assistance required to promote small business growth, expansion, and productively within the State. The SBDC shall also ensure that a full range of business development and technical assistance services are made available to small businesses located in rural areas.

The degree to which SBDC resources are directed towards specific areas of assistance is determined by local community needs, SBA priorities and SBDC Program objectives and agreed upon the SBA district and the SBDC.

The SBDC must offer quality training to improve the skills and knowledge of existing and prosective small business owners. As a general guideline, SBDCs should emphasize the provision of training in specialized areas other than basic small business management subjects. SBDCs should also emphasize training designed to reach particular audiences such as members of SBA priority and special emphasis groups.

SBDC Program Requirements

The SBDC is responsible to the SBA for ensuring that all programmatic and financial requirements imposed upon them by statute or agreement are met. The SBDC must assure that quality assistance and training in management and technical areas are provided to the State small business community through the State SBDC network. As a condition of this agreement, the SBDC must

perform, but not limited to, the following activities:

(a) The SBDC ensures that services that services are provided as close as possible to small business population centers. This is accomplished through the establishment of SBDC subcenters.

(b) The SBDC ensures that lists of local and regional private consultants are maintained at the lead SBDC and each SBDC subcenter. The SBDC utilizes and provides compensation to qualified small business vendors such as private management consultants, private consulting engineers, and private testing laboratories.

(c) The SBDC is responsible for the development and expansion of resources within the State, particularly the development of new resources to assist small business that are not presently associated with the SBA district office.

(d) The SBDC ensurese that working relationships and open communications exist within the financial and investment communities, and with legal associations, private consultants, as well as small business groups and associations to help address the needs of the small business community.

(e) The SBDC ensures that assistance is provided to SBA special emphasis groups throughout the SBDC network. This assistance shall be provided to veterans, women, exporters, the handicapped, and minorities as well as any other groups designated a priority by SBA. Services provided to special emphasis groups shall be performed as part of the Cooperative Agreement.

Advance Understandings

The Lead SBDC and all SBDC subcenters shall operate on a forty (40) hour week basis, or during the normal business hours of the State or Host Organization, throughout the calendar year. The amount of time allowed the Lead SBDC and subcenters for staff vacations and holidays shall conform to the policy of the Host organization.

Dated: June 13, 1990.

Susan Engeleiter,

Administrator.

Addresses of Relevant SBDC Directors

Dr. Jeff Gibbs, State Director, University of Alabama/B'ham, 1717 11th Ave. South, Suite 419, Birmingham, Alabama 35294, (205) 934–7260

Mr. John O'Connor, State Director, University of Connecticut, Box U–41, Room 422, 368 Fairfield Road, Storrs, Connecticut 06268, (203) 486–4135

Ms. Linda Fayerweather, State Director, University of Delaware, Suite 005–Purnell Hall, Newark, Delaware 19711, (302) 451–2747

Mr. Max E. Summers, State Director, University of Missouri, Suite 300, University Place, Columbia, Missouri 65211, (314) 882–1348

Mr. Jose Romaguera, SBDC Director, University of Puerto Rico, Box 5253—College Station, Mayaguez, Puerto Rico 00709, (809) 834–3590 or 834–3790

Mr. Craig Bean, Acting Region Director, Texas Tech University, 1313 Broadway, Suite 1, Lubblock, Texas 79401, (806) 744–5343

Dr. Solomon Kabuka, Jr., SBDC Director, University of the Virgin Islands, Grand Hotel Building, Annex B, P.O. Box 1087, St. Thomas, US Virgin Islands 00804, (809) 776–3206

Dr. William Blachman, Acting State Director, University of Alaska/Anchorage, 430 West 7th Avenue, Suite 115, Anchorage, Alaska 99501, (907) 274–7232

Mr. Raleigh Byars, State Director, University of Mississippi, Old Chemistry Building, Suite 216, University, Mississippi 38677, (601) 234–2120

Mr. James L. King, State Director, State University of New York, SUNY (Downstate), SUNY Plaza, S–523, Albany, New York 12246, (518) 443–5398

Mr. Jack Brown, State Director, Ohio Department of Development, 30 East Broad Street, Columbus, Ohio 43266–1001, (614) 466–5111

Dr. Norbet R. Dettman, Region Director, Dallas Community College, 1402 Corinth Street, Dallas, Texas 75215, (214) 565–5831

Mr. Richard Wilson, Region Director, University of Texas/San Antonio, San Antonio, Texas 78285–0660, (512) 224–0791

Ms. Eloise Jack, State Director, Governor's Office of Community and Industrial Development, 1115 Virginia Street, East, Charleston, West Virginia 25310, (304) 348–2960

Mr. MacRay Bryant, State Director, Casper Community College, 130 North Ash, Suite A, Casper, Wyoming 82601, (307) 235–4825

Mr. A. Elliott Rittenhouse, State Director, MD Department of Economic and Employment Development, 217 East Redwood Street, 10th Floor, Baltimore, Maryland 21202, (301) 333–6608

[FR Doc. 90–14219 Filed 6–19–90; 8:45 am]

BILLING CODE 8025–01–M

Action Subject to Intergovernmental Review

AGENCY: Small Business Administration.

ACTION: Notice of action subject to intergovernmental review under Executive order 12372.

SUMMARY: This notice provides for public awareness of SBA's intention to refund eight presently existent Small Business Development Centers (SBDCs) on September 30, 1990. Currently there are 56 SBDCs operating in the SBDC program. The following SBDCs are intended to be refunded: Iowa, Kentucky, Louisiana, Massachusetts, Michigan, New York (Upstate), Texas (Houston), and Vermont. This notice also provides a description of the SBDC program by setting forth a condensed version of the program announcement which has been furnished to each of the SBDCs to be refunded. This publication is being made to provide the State single points of contact, designated pursuant to Executive Order 12372, and other interested State and local entities, the opportunity to comment on the proposed refunding in accord with the Executive Order and SBA's regulations found at 13 CFR part 135.

EFFECTIVE DATE: September 18, 1990.

ADDRESS: Comments should be addressed to Ms. Janice E. Wolfe, Associate Administrator for SBDC Program, U.S. Small Business Administration, 1441 L Street, NW., Wash. DC 20416.

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In accord with these regulations, specifically § 135.4, SBA is publishing this notice to provide public awareness of the pending application of eight presently existent Small Business Development Centers (SBDCs) for refunding. Also, published herewith is an annotated program announcement describing the SBDC program in detail.

This notice is being published three months in advance of the expected date of refunding these SBDCs. Relevant information identifying these SBDCs and providing their mailing address is provided below. In addition to this publication, a copy of this notice is being simultaneously furnished to the affected State single point of contact which has been established under the Executive Order.

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SBDC Services

The specific types of services to be offered are developed in coordination with the SBA district office which has jurisdiction over a given SBDC. SBDCs emphasize the provision of indepth, high-quality assistance to small business owners or prospective small business owners in complex areas that require specialized expertise.

These areas may include, but are not limited to: management, marketing, financing, accounting, strategic planning, regulation and taxation, capital formation, procurement assistance, human resource management, production, operations, economic and business data analysis, engineering, technology transfer, innovation and research, new product development, product analysis, plant layout and design, agri-business, computer application, business law information, and referral (any legal services beyond basic legal information and referral require the endorsement of the State Bar Association,) exporting, office automation, site selection, or any other areas of assistance required to promote small business growth, expansion, and productivity within the State. The SBDC shall also ensure that a full range of business development and technical assistance services are made available to small businesses located in rural areas.

The degree to which SBDC resources are directed towards specific areas of assistance is determined by local community needs, SBA priorities and SBDC Program objectives and agreed upon by the SBA district office and the SBDC.

The SBDC must offer quality training to improve the skills and knowledge of existing and prospective small business owners. As a general guideline, SBDCs should emphasize the provision of training in specialized areas other than basic small business management subjects. SBDCs should also emphasize training designed to reach particular audiences such as members of SBA priority and special emphasis groups.

SBDC Program Requirements

The SBDC is responsible to the SBA for ensuring that all programmatic and financial requirements imposed upon them by statute or agreement are met. The SBDC must assure that quality assistance and training in management and technical areas are provided to the State small business community through the State SBDC network. As a condition of this agreement, the SBDC must perform, but not be limited to, the following activities:

(a) The SBDC ensures that services are provided as close as possible to small business population centers. This is accomplished through the establishment of SBDC subcenters.

(b) The SBDC ensures that lists of local and regional private consultants are maintained at the lead SBDC and each SBDC subcenter. The SBDC utilizes and provides compensation to qualified small business vendors such as private management consultants, private consulting engineers, and private testing laboratories.

(c) The SBDC is responsible for the development and expansion of resources within the State, particularly the development of new resources to assist small business that are not presently associated with the SBA district office.

(d) The SBDC ensures that working relationships and open communications exist within the financial and investment communities, and with legal associations, private consultants, as well as small business groups and associations to help address the needs of the small business community.

(e) The SBDC ensures that assistance is provided to SBA special emphasis groups throughout the SBDC network. This assistance shall be provided to veterans, women, exporters, the handicapped, and minorities as well as any other groups designated a priority by SBA. Services provided to special emphasis groups shall be performed as part of the Cooperative Agreement.

Advance Understandings

The Lead SBDC and all SBDC subcenters shall operate on a forty (40) hour week basis, or during the normal business hours of the State or Host Organization, throughout the calendar year. The amount of time allowed the Lead SBDC and subcenters for staff vacations and holidays shall conform to the policy of the Host organization.

Dated: June 13, 1990.

Susan Engeleiter,

Administrator.

Addresses of Relevant SBDC Directors

Mr. Norris Elliott, State Director, University of Vermont Extension Service, Morrill Hall, Burlington, Vermont 05405, (802) 656–4479.

Mr. Jerry Owen, State Director, University of Kentucky, 18 Porter Building, Lexington, Kentucky 40506–0205, (606) 257–7668.

Mr. John Ciccarelli, State Director, University of Massachusetts, School of Management, Amherst, Massachusetts 01003, (413) 549–4930—Ext. 303.

Mr. James L. King, State Director, State University of New York, SUNY (Upstate), State University Plaza, Albany, New York 12246, (518) 443–5398.

Mr. Ronald Manning, State Director, Iowa State University, College of Business Administration, 137 Lynn Avenue, Ames, Iowa 50010, (515) 292–6351.

Dr. John Baker, State Director, Northeast Louisiana University, 700 University Avenue, Monroe, Louisiana 71209, (318) 342–5506.

Dr. Norman Schlafmann, State Director, Wayne State University, 2727 Second Avenue, Detroit, Michigan 48201, (313) 577–4848.

Dr. Elizabeth Gatewood, Region Director, University of Houston, 601 Jefferson, Suite 2330, Houston, Texas 77002, (713) 752–8400.

[FR Doc. 14220 Filed 6–19–90; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Participation by Minority Business Enterprise in Department of Transportation Programs

AGENCY: Office of the Secretary, DOT.

ACTION: Notice: 1989 inflation adjustment of size limits on small businesses participating in the DOT disadvantaged business enterprise program.

SUMMARY: Under the statutes governing the Department's Disadvantaged Business Enterprise ("DBE") Program, firms are not considered to be small business concerns, and hence are not eligible DBEs, once their average annual receipts over the preceeding three fiscal years reaches $14 million. These statutes, and the DOT rule implementing them, provide for the Secretary to adjust the $14 million figure for inflation. On February 14, 1990, the Secretary published the revised small business size limit ($14,650,000), which is currently in effect after adjustment for inflation in 1988. This notice revises the small business size limit after adjustment for inflation in 1989.

EFFECTIVE DATE: June 20, 1990.

FOR FURTHER INFORMATION CONTACT: Bradford K. Talamon, Office of the Assistant General Counsel for Environmental, Civil Rights and General Law, 400 7th St., SW., Room 10102, Washington, DC 20590; Telephone: (202) 366–9161.

SUPPLEMENTARY INFORMATION: In section 106(c)(2) of the Surface Transportation and Uniform Relocation Assistance Act of 1987 ("STURAA") and section 105(f) of the Airport and Airway Safety and Capacity Expansion Act of 1987, Congress determined that in order to ensure that the DBE Program meets its objective of helping small businesses owned and controlled by socially and economically disadvantaged individuals become self-sufficient and able to compete in the market with non-disadvantaged firms, DBE firms should no longer be eligible for the program once their average annual receipts over the preceding three fiscal years reaches $14 million. The definition of "small business concern" in 49 CFR 23.62 implements these provisions of the statutes.

Both statutes make the $14 million figure subject to adjustment by the Secretary for inflation. The regulation provides that the Secretary shall make such adjustments from time to time. On February 14, 1990, the Secretary published the revised small business size limit ($14,650,000), which is currently in effect after adjustment for inflation in 1988. This notice revises the small business size limit after adjustment for inflation in 1989.

The Department of Commerce, Bureau of Economic Analysis, prepares constant dollar estimates of state and local government purchases of goods and services by deflating current dollar estimates by suitable price indexes. These indexes include purchases of durable goods, nondurable goods, financial and other services, structures (11 types of new construction, net purchase of existing residential structures, nonresidential structures and maintenance repair services) and compensation of employees. By use of these price deflators, we are able to adjust dollar figures in both past and future years for inflation.

DOT's largest programs extend federal financial assistance through FHWA, UMTA and FAA to state and local governments or entities created by them. Through its programs, DOT provides funding for contracts under these programs for goods and services which involve transportation-related projects and are awarded by state and local governments. Given the nature of DOT's DBE Program, adjusting the $14 million size limit on small businesses in the same manner in which inflation adjustments are made to the costs of state and local government purchases of goods and services is simple, accurate, fair and in accordance with the statutory command in both section 106(c)(2) of the STURAA and section 105(f) of the Airport and Airway Safety and Capacity Expansion Act of 1987.

The inflation rate of the cost of purchases by state and local governments for the current year is calculated by dividing the price deflator for 1989 (135.0) by the 1988 price deflator (128.7). The result is 1.0490, which represents an inflation rate of 4.90 percent from December 31, 1988 to December 31, 1989. Multiplying the $14,650,000 figure by 1.0490 equals $15,367,850 which will be rounded off to the nearest $10,000, or $15,370,000.

Therefore, until further notice, if a firm's average gross annual receipts over the preceding three years does not exceed $15,370,000, it does not exceed the small business size limit contained in section 106(c)(2) of the STURAA, section 105(f) of the Airport and Airway

Safety and Capacity Expansion Act of 1987 and 49 CFR 23.62.

This decision avoids the complexity of making different adjustments for inflation for different industries and types of firms within industries. The small business size limit will be adjusted annually in future notices of this type.

This notice only affects the $14 million small business size limit on the DOT DBE Program. The SBA size limits contained in 13 CFR part 121 remain unaffected and are not subject to inflation adjustments by DOT.

Issued in Washington, DC, June 13, 1990.

Samuel K. Skinner,

Secretary of Transportation.

[FR Doc. 90-14202 Filed 6-19-90; 8:45 am]

BILLING CODE 4910-62-M

Office of the Secretary

Aviation Proceedings: New Route Opportunities (U.S.-U.S.S.R.)

By this notice we invite certificate applications from all U.S. carriers interested in serving the following U.S.-U.S.S.R. routes:

From a point or points in the United States via intermediate points on a North Atlantic routing to Moscow, Leningrad, Kiev, Riga, Minsk, and Tbilisi.[1] From a point or points in the United States on a North Pacific routing to Magadan and Khabarovsk.

On June 1, 1990, the United States and the Union of Soviet Socialist Republics entered into an Air Transport Agreement whereby expanded civil aviation rights are now available to the carriers of both countries.

Effective April 1, 1991, the U.S. may designate an additional four combination air carriers (in addition to Pan American, currently the only U.S. carrier designated to serve the Soviet Union) and two all-cargo carriers for U.S.-U.S.S.R. services. U.S. carriers will be permitted to provide new services to Kiev, Riga, Minsk, Tbilisi, Magadan, and Khabarovsk, in addition to current rights to Moscow and Leningrad, subject to the frequency limits described below.[2]

From April 1, 1991, through March 31, 1992, the U.S.-designated airlines (collectively, including Pan American's frequencies), may operate up to 22 roundtrip equivalent combination frequencies per week between the United States and Moscow/Leningrad.[3] Beginning April 1, 1992, and continuing through March 31, 1993, the allowable frequencies increase to a total of 37 per week in the U.S.-Moscow/Leningrad markets.

From April 1, 1991, through March 31, 1993, the U.S.-designated combination airlines may operate up to 10 roundtrip equivalent combination frequencies per week between the United States and Kiev, Riga, Minsk, Tbilisi, Magadan, and Khabarovsk, subject to the condition that no one of these cities receives more than seven weekly roundtrip equivalent frequencies.

From April 1, 1991, through March 31, 1992, the U.S. designated all-cargo airlines may operate up to 10 roundtrip equivalent frequencies per week between the United States and Moscow, Leningrad, Kiev, Riga, Minsk, Tbilisi, Magadan, and Khabarovsk, provided no one of these cities receives more than seven roundtrip equivalent frequencies. Beginning April 1, 1992, the all-cargo frequencies increase to 11 flights per week.

In view of these new route opportunities, we invite carriers to file applications for certificate authority to serve the markets listed above no later than July 3, 1990. Competing applications and answers shall be due no later than July 13, 1990, and responsive pleadings no later than July 18, 1990.[4] Carriers which have already filed for authority to serve between the U.S. and U.S.S.R.[5] need not refile unless they wish to supplement their requests as a result of changed circumstances, etc.[6]

Applications should be filed pursuant to subpart Q and part 302 of the Department's regulations. Applications should be filed with the Department's Docket Section, Room 4107, 400 Seventh Street SW., Washington, DC 20590. As the route rights are limited and the agreement extends only through March 31, 1993, we intend to award the authority at issue in the form of 3-year, temporary, experimental certificates under section 401(d) of the Act. Uncontested and noncontroversial applications will be granted by final order. Other procedures, as necessary, shall be established by Department order.

Dated: June 14, 1990.

Jeffrey N. Shane,

Assistant Secretary for Policy and International Affairs.

[FR Doc. 90-14203 Filed 6-19-90; 8:45 am]

BILLING CODE 4910-62-M

[1] Not more than two U.S. combination and one U.S. all-cargo airlines may operate between the city-pair markets Moscow/Leningrad-New York/Washington. Not more than two U.S. airlines (*i.e.*, two combination, two all-cargo or one combination and one all-cargo airline) may operate between any other U.S.-U.S.S.R. city-pair.

[2] The agreement does not provide for beyond services by U.S. carriers. Therefore, carriers should not include such services in their applications.

[3] Designated airlines may use wide or narrow-bodied aircraft subject to the following capacity equivalency conversion factors: Combination services: B-737/B-727-IL-62M/TU-154=1.0; A-310/Stretched DC-8/B-757/B-767/A300-605R with 218 seats/IL-86 with 220 seats=1.3; L-1011/A-300/DC-10/A300-605R with 267 seats/IL-96/IL-86 with 250 seats=1.5; B-747=2.0. All-cargo services: L-100/B-727/TU-154=0.5; IL-76/DC-8=1.0; DC-10-30CF=1.3; MD-11F=1.5; B-747/AN-124=2.0.

[4] As the new authority is not available until April 1991, at this time we do not intend to entertain exemption applications for U.S.-U.S.S.R. services.

[5] Alaska Airlines, Inc., in Docket 45390, American Airlines, Inc., in Docket 46978, Delta Air Lines, Inc., in Dockets 46962 and 46963, and United Air Lines, Inc., in Docket 46969.

[6] Interested parties may file competing applications and responsive pleadings to applications already filed in accordance with the dates specified above.

Privacy Act of 1974: System of Records USCG Civilian Personnel Security Program

The Department of Transportation herewith publishes a proposal to alter a system of records.

Any person or agency may submit written comments on the proposed altered system to the U.S. Coast Guard (OIS-2), ATTN: Mr. Ronald Seidman, Chief, Security Branch, 2100 Second Street, SW., Washington, DC 20593-0001. Comments to be considered must be received by July 6, 1990.

If no comments are received, the proposed changes will become effective 30 days from the date of issuance. If comments are received, the comments will be considered and where adopted, the document will be republished with the changes.

Issued in Washington, DC, June 7, 1990.

Jon Seymour,

Assistant Secretary for Administration.

DOT/CG 633

SYSTEM NAME:

Coast Guard Personnel Security Program.

SYSTEM LOCATION:

Office of Law Enforcement and Defense Operations, U.S. Coast Guard, 2100 Second Street, SW., Washington, DC 20593-0001.

Decentralized segments are located at military or civilian personnel offices serving the person's duty station or the Office of the Director of Auxiliary serving the Auxiliarist's flotilla.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Coast Guard military members; civilian applicants, employees and former employees; detailees from other Federal agencies; contract applicants and employees; and Coast Guard Auxiliarists.

CATEGORIES OF RECORDS IN THE SYSTEM:

a. Records of security clearances issued/terminated;

b. Investigative files which serve as the basis for granting or denying a security clearance (civilian and auxiliary personnel only), determining suitability for hire and for assignment to sensitive positions (not in decentralized segments); and

c. Correspondence and records concerning security actions.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

See Prefatory Statement of General Routine Uses.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

File folders, index cards, and automated data.

RETRIEVABILITY:

Records are retrieved by name or social security number.

SAFEGUARDS:

Records are kept in lockable cabinets and safes, and protected automated systems. Access is controlled to work areas which are locked and alarmed. Individual identification is required for users of the records..

RETENTION AND DISPOSAL:

Destroy upon notification of death or not later than 5 years after separation or transfer of the individual or no later than 5 years after contract relationship expires, whichever is applicable. Investigative reports and related material will be destroyed or returned in accordance with the investigating agency instructions. The SF 312 will be destroyed 50 years from date of execution.

SYSTEM MANAGER(S) AND ADDRESS:

Office of Law Enforcement and Defense Operations, U.S. Coast Guard, 2100 Second Street, SW., Washington, DC 20593–0001.

NOTIFICATION PROCEDURE:

Commandant (G–TIS), U.S. Coast Guard, 2100 Second Street, SW., Washington, DC 20593–0001.

Written request must be signed by the individual whose record is being requested, or if signed by a person other than the individual, must specify the relationship to that individual.

RECORD ACCESS PROCEDURES:

Access may be obtained by writing to:

a. Commandant (G–TIS) at the address in "Notification procedure" for records in the centralized records.

b. The military or civilian personnel office serving the individual's duty station for records in the decentralized segment.

c. The Director of Auxiliary serving the Auxiliarist's flotilla of records in the decentralized segment.

Access requests for records containing information which originated with or were obtained by a part of the Federal Government, other than the Coast Guard, shall be referred to that agency for release determination.

CONTESTING RECORD PROCEDURES:

Same as "Record access procedure."

RECORD SOURCE CATEGORIES:

The individual, Department of Transportation employees and records, other Government agencies.

SYSTEMS EXEMPTED FROM CERTAIN PROVISIONS OF THE ACT:

Exemptions: Portions of this system of records may be exempt from disclosure under the provisions of 5 U.S.C. 552a(k)(5), which provide, in part, that investigatory material compiled solely for the purpose of determining suitability, eligibility, or qualifications for Federal civilian employment, military service, Federal contracts, or access to classified information may be withheld from disclosure but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under and express promise that the identify of the source would be held in confidence, or, prior to December 31, 1974, under an implied promise that the identity of the source would be held in confidence.

Portions of this system of records may be exempt from disclosure under the provisions of 5 U.S.C. 552a(k)(7), which provide, in part, that evaluation material used to determine potential for promotion in the Armed Services may be withheld from disclosure but only to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an expressed promise that the identity of a source would be held in confidence, or, prior to December 31, 1974, under an implied promise that the identity of the source would be held in confidence.

Narrative Statement, Department of Transportation, Office of the Secretary, On Behalf of the United States Coast Guard, For Alteration of the USCG Civilian Personnel Security Program

The Office of the Secretary, on behalf of the Coast Guard, proposes to amend the Coast Guard Civilian Personnel Security Program System, DOT/CG 633, to better reflect anticipated changes in military and civilian personnel security programs as described under the appropriate headings prepared for publication in the **Federal Register**.

The purpose of this notice is to more accurately describe this system of records in light of the below listed changes to agency practices. The first of three major revisions will change the system name from "Coast Guard Civilian Personnel Security Program" to "Coast Guard Personnel Security Program." This allows military and civilian security files to be maintained together. The second major change adds a new category of records to the system, specifically, security files on Coast Guard Auxiliarists. This will allow a security record to be maintained on them as well. Finally, this revision will change the system from Chief, Office of Personnel (Commandant (G–PS/6)) to Office of Law Enforcement and Defense Operations (Commandant (G–O)).

The changes include amendments to: System name, System location, Categories of individuals covered by the system, Routine uses of records maintained in the system including categories of users and the purposes of such uses, Storage, Retrievability, Safeguards, Retention and disposal, System manager(s) and address, Notification procedure, Record access procedures, and Record source categories.

This proposed amendment of an existing record system will have minimal effect on the privacy interests of the general public. This record system impacts only those persons who choose to enter into a contractual employment or volunteer relationship with the Coast Guard.

A description of the steps taken to safeguard these records is given under the appropriate heading of the attached Federal Register system of records notice.

The purpose of this report is to comply with Office of Management and Budget Circular, A–130, Appendix I, dated December 12, 1985.

[FR Doc. 90–14204 Filed 6–19–90; 8:45 am]

BILLING CODE 4910–62–M

Sunshine Act Meetings

Federal Register
Vol. 55, No. 119
Wednesday, June 20, 1990

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

COMMODITY FUTURES TRADING COMMISSION

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 55 FR 23833.

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 3:00 p.m., Wednesday, June 20, 1990.

CHANGE IN THE MEETING: The Commission has canceled the closed meeting to discuss enforcement matters.

CONTACT PERSON FOR MORE INFORMATION: Jean A. Webb, Secretary of the Commission.

Jean W. Webb,
Secretary of the Commission.
[FR Doc. 90-1446 Filed 6-18-90; 3:08 pm]
BILLING CODE 6351-01-M

INTERSTATE COMMERCE COMMISSION

Notice of Closed Meeting

TIME AND DATE: 10 a.m.; Wednesday, June 27, 1990.

PLACE: Room 4225, Interstate Commerce Commission, 12th Street & Constitution Avenue, NW., Washington, DC 20423.

STATUS: Closed Meeting.

The Commission voted to hold a closed conference to deliberate and decide internal staffing and personnel matters with respect to carrying out the functions of the Commission pursuant to the exemptive provisions of 5 U.S.C. 552b(c)(2).

MATTERS TO BE DISCUSSED: Internal Staffing and Personnel Matters.

CONTACT PERSON FOR MORE INFORMATION: A. Dennis Watson, Office of Government and Public Affairs, Telephone (202) 275-7252.

Noreta R. McGee,
Secretary.
[FR Doc. 90-14424 Filed 6-18-90; 1:47 pm]
BILLING CODE 7035-01-M

NATIONAL MEDIATION BOARD

TIME AND DATE: 2:00 p.m., Wednesday, July 11, 1990.

PLACE: Board Hearing Room, 8th floor, 1425 K Street, NW, Washington, DC.

STATUS: Open.

MATTERS TO BE CONSIDERED: 1. Ratification of the Board actions taken by notation voting during the month of June, 1990.

2. Other priority matters which may come before the Board for which notice will be given at the earliest practicable time.

SUPPLEMENTARY INFORMATION: Copies of the monthly report of the Board's notation voting actions will be available from the Executive Director's office following the meeting.

CONTACT PERSON FOR MORE INFORMATION: Mr. William A. Gill, Jr., Acting Executive Director, Tel: (202) 523-5920.

Date of notice: June 8, 1990.

William A. Gill, Jr.,
Executive Director, National Mediation Board.
[FR Doc. 90-14372 Filed 6-18-90; 1:19 pm]
BILLING CODE 7550-01-M

NUCLEAR REGULATORY COMMISION

DATE: Weeks of June 18, 25, July 2, and 9, 1990.

PLACE: Commissioners' Conference Room, 11555 Rockville, Pike, Rockville, Maryland.

STATUS: Open and Closed.

MATTERS TO BE CONSIDERED:

Week of June 18

Wednesday, June 20

2:00 p.m.—Briefing on NUREG—1150 Peer Review Group Status (Public Meeting)

Week of June 25 (Tentative)

Wednesday, June 27

9:00 a.m.—Periodic Briefing on Operating Reactors and Fuel Facilities (Public Meeting)

11:00 a.m.—Affirmation/Discussion and Vote (Public Meeting) (if needed)

Week of July 2 (Tentative)

There are no Commission meetings scheduled for the Week of July 2.

Week of July 9 (Tenative)

There are no Commission meetings scheduled for the Week of July 9.

Note.—Affirmation sessions are initially scheduled and announced to the public on a time-reserved basis. Supplementary notice is provided in accordance with the Sunshine Act as specific items are identified and added to the meeting agenda. If there is no specific subject listed for affirmation, this means that no item has as yet been identified as requiring any Commission vote on this date.

To verify the status of meetings call (Recording)—(301) 492-0292.

CONTRACT PERSON FOR MORE INFORMATION: William Hill (301) 492-1661.

William M. Hill, Jr.,
Office of the Secretary.
[FR Doc. 90-14382 Filed 6-18-90; 1:20 pm]
BILLING CODE 7590-01-M

Corrections

Federal Register
Vol. 55, No. 119
Wednesday, June 20, 1990

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lincomycin

Correction

In rule document 90-13317 beginning on page 23423, in the issue of Friday, June 8, 1990, make the following correction:

§ 558.325 [Corrected]

On page 23424, in the first column, in § 558.325, in the last line, "slaughter." should read "slaughter".

BILLING CODE 1505-01-D

NATIONAL ARCHIVES AND RECORDS ADMINISTRATION

Office of the Federal Register

List of Libraries That Have Announced Availability of Federal Register and Code of Federal Regulations

Correction

In the Reader Aids section, beginning on page 20026, in the issue of Monday, May 14, 1990, make the follwing correction: In the fourth line of the first paragraph, the name and the address of the Library should read: Library Programs Service, U.S. Government Printing Office, Washington, DC 20401

BILLING CODE 1505-01-D

federal register

Wednesday
June 20, 1990

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 347

Skin Protectant Drug Products for Over-the-Counter Human Use; Diaper Rash Products; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 347

[Docket No. 78N-021D]

RIN 0905-AA06

Skin Protectant Drug Products for Over-the-Counter Human Use; Proposed Rulemaking for Diaper Rash Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking amending the tentative final monograph (proposed rule) for over-the-counter (OTC) skin protectant drug products. The proposed rulemaking would establish conditions under which OTC skin protectant drug products for the treatment or prevention of diaper rash are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the statement on OTC drug products for the treatment of diaper rash of the Advisory Review Panel on OTC Miscellaneous External Drug Products, public comments on an advance notice of proposed rulemaking that was based on that statement, and public comments on the notice of proposed rulemaking for OTC skin protectant drug products. (See the **Federal Register** of February 15, 1983; 48 FR 6820.) The agency's proposals concerning the use of other OTC diaper rash drug products are being published elsewhere in this issue of the **Federal Register**. These proposals are part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed rulemaking before the Commissioner of Food and Drugs by December 17, 1990. The agency is allowing a period of 180 days for comments and objections instead of the normal 60 days for the following reasons: (1) The concurrent publication of four rulemakings regarding OTC diaper rash drug products and (2) this document contains the agency's initial evaluation of the submissions of data on OTC diaper rash drug products that were made to, but not reviewed by, the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel). New data by June 20, 1991. Comments on the new data by August 20, 1991. Written comments on the agency's economic impact determination by December 17, 1990.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 7, 1982, FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), advance notices of proposed rulemaking and reopened the administrative records for OTC topical antifungal drug products (47 FR 39464), topical antimicrobial drug products (47 FR 39406), external analgesic drug products (47 FR 39412), and skin protectant drug products (47 FR 39436) to allow for consideration of a statement on OTC drug products for the treatment of diaper rash prepared by the Miscellaneous External Panel, which was the advisory review panel responsible for evaluating data on the active ingredients used for the treatment of diaper rash. Interested persons were invited to submit comments by December 6, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by January 5, 1983.

In the **Federal Register** of December 28, 1982 (47 FR 57738), in response to a request for an extension of time, the comment period and reply comment period for OTC skin protectant drug products were extended to February 4, 1983, and to March 7, 1983, respectively.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

Five drug manufacturers, one trade association, and one manufacturer of diapers submitted comments. Most of these comments are general in scope and were submitted to more than one of the four rulemakings mentioned above. In those cases where the same comments were submitted to more than one rulemaking, the comments are being addressed only once—in this notice of proposed rulemaking to amend the notice of proposed rulemaking for OTC skin protectant drug products. Copies of the comments received are on public display in the Dockets Management Branch.

The Panel provided a general statement on OTC drug products for the treatment of diaper rash, but did not review individual ingredients nor develop labeling for diaper rash drug products. The agency is aware that a number of diaper rash drug products are labeled for both the treatment and prevention of diaper rash. Therefore, the agency is expanding the scope of this rulemaking to include drug products labeled for both or either use.

In the **Federal Register** of February 15, 1983 (48 FR 6820), the agency published a tentative final monograph (proposed rule) for OTC skin protectant drug products. The agency issued this notice after considering the report and recommendations of the Advisory Review Panel on OTC Topical Analgesic, Antirheumatic, Otic, Burn, and Sunburn Prevention and Treatment Drug Products (Topical Analgesic Panel) and public comments on an advance notice of proposed rulemaking that was based on those recommendations.

Interested persons were invited to submit comments by April 18, 1983, new data by February 15, 1984, and comments on the new data by April 16, 1984. In response to that notice, four drug manufacturers submitted comments concerning the use of skin protectant ingredients for diaper rash. The agency is also addressing these comments in this notice of proposed rulemaking. Copies of the comments received are on public display in the Dockets Management Branch (address above).

In this notice of proposed rulemaking, FDA responds to public comment and states for the first time its position on OTC skin protectant drug products for the treatment or prevention of diaper rash. Final agency action on this matter will occur with the publication at a future date of a final rule relating to OTC skin protectant drug products for use in diaper rash. Other documents concerning the use of OTC topical antifungal drug products, OTC topical antimicrobial drug products, and OTC external analgesic drug products for the treatment or prevention of diaper rash are being published separately, elsewhere in this issue of the **Federal Register**. This proposal constitutes FDA's tentative adoption of the Panel's statement on OTC skin protectant drug products for use in diaper rash as modified on the basis of the comments received and the agency's independent evaluation of the Panel's statement.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any

testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the **Federal Register**. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the **Federal Register** of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the advance notices of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

The agency has reviewed the comments submitted to this rulemaking and, as noted above, determined that most of the comments were submitted to more than one of the four rulemakings related to OTC diaper rash drug products. The majority of the comments are general in scope or deal primarily with the use of skin protectant active ingredients. The agency has decided to address all of these general comments in a single rulemaking, which is this notice of proposed rulemaking to amend the tentative final monograph for OTC skin protectant drug products. Accordingly, the general comments regarding diaper rash as well as the portions of the comments that concerned skin protectant active ingredients are addressed below. The general comments applicable to the other three affected rulemakings are incorporated into those rulemakings, respectively.

A. General Comments

1. One comment contended that OTC drug monographs are interpretive, as opposed to substantive, regulations. The comment referred to statements on this issue submitted earlier to other OTC drug rulemaking proceedings.

The agency addressed this issue in paragraphs 85 through 91 of the preamble to the procedures for classification of OTC drug products, published in the **Federal Register** of May 11, 1972 (37 FR 9464), and in paragraph 3 of the preamble to the tentative final monograph for antacid drug products, published in the **Federal Register** of November 12, 1973 (38 FR 31260). FDA reaffirms the conclusions stated in those documents. Court decisions have confirmed the agency's authority to issue substantive regulations by rulemaking. (See, e.g., *National Nutritional Foods Association* v. *Weinberger*, 512 F.2d 688, 696–98 (2d Cir. 1975) and *National Association of Pharmaceutical Manufacturers* v. *FDA*, 487 F. Supp. 412 (S.D.N.Y. 1980), aff'd, 637 F.2d 887 (2d Cir. 1981).)

2. Two comments requested that a separate and distinct rulemaking be established to encompass consideration of the safety and efficacy of OTC drug products for the treatment and prevention of diaper rash. The comments contended that diaper rash drug products represent a well-established, separate, and distinctive product category and, thus, should be the subject of a separate OTC drug monograph. As an alternative to a separate monograph, one of the comments suggested that diaper rash drug products could be a clearly identifiable subsection of the monograph for OTC skin protectant drug products because diaper rash drug products, almost without exception, contain at least one skin protectant ingredient, or a combination of skin protectant ingredients, and many of these ingredients are already included in the rulemaking for OTC skin protectant drug products. This comment added that diaper rash products are considered as a separate product category in the *Handbook of Nonprescription Drugs* (Ref. 1).

The agency agrees that drug products for the treatment and prevention of diaper rash would be suitable for a separate and distinct rulemaking, but believes, as suggested by one of the comments, that these products could be included as a clearly identifiable subsection of the monograph for OTC skin protectant drug products. Because most of the ingredients used to treat and prevent diaper rash are also used as skin protectants, the agency concludes that incorporating the diaper rash ingredients and claims as a subpart of the skin protectant monograph will eliminate unnecessary duplication and make it easier for interested parties to locate the regulatory information related to these products. Likewise, any external analgesic, antimicrobial, or antifungal active ingredients that are Category I for diaper rash can be included in an appropriate subpart of their respective monographs.

Reference

(1) Smith, G.H., "Diaper Rash and Prickly Heat Products," *in* "Handbook of Nonprescription Drugs," 7th Ed., American Pharmaceutical Association, Washington, pp. 605–614, 1982.

3. Referring to the Panel's general discussion on diaper rash (47 FR 39406 at 39409, 39412 at 39416, 39436 at 39440, and 39464 at 39467), one comment requested removal of some of the Panel's statements regarding disposable diapers with a plastic backing. Contending that the Panel's remarks were anecdotal or superfluous and not supported by scientific data, the comment stated that these remarks were inappropriate for inclusion in an OTC drug monograph unless substantiated by

data acceptable to the scientific community.

The OTC drug review procedures do not preclude a panel from expressing its opinion about factors that may be related to the use of drug products being evaluated. In this instance, the Panel discussed disposable diapers with a plastic backing in relation to occlusion as a factor that may affect diaper rash. However, the Panel did not propose any labeling regarding the use of disposable diapers with a plastic backing.

Other panels have also discussed occlusion in relation to drug products that they reviewed. For example, the Topical Analgesic Panel discussed occlusion in relation to children under 2 years of age in its report on OTC external analgesic drug products stating, "Ingredients under occlusion may possibly be corrosive to the infant's skin," (44 FR 69768 at 69774). In its report on topical antifungal drug products, the Advisory Review Panel on OTC Antimicrobial (II) Drug Products (Antimicrobial II Panel) referred to "occlusive socks and stockings that increase sweating and favor the development of athletes foot," (47 FR 12480 at 12489). Disposable diapers are consumer products, not drugs, and therefore are not covered by OTC drug rulemaking proceedings. Consequently, the agency does not believe that there is a need to remove the requested statements from the Panel's discussion. Further, there is no need for any person to submit additional data or comments regarding disposable diapers with a plastic backing because such articles are outside the scope of this rulemaking and will not be further addressed in the tentative final monographs for OTC diaper rash drug products.

B. Comments on Labeling

4. Two comments contended that FDA cannot legally, and should not as a matter of policy, prescribe exclusive lists of terms for the indications for use for OTC drug products, thus prohibiting alternative OTC labeling terminology which is truthful, not misleading, and intelligible to the consumer. One comment added that its views on this subject were presented to FDA in connection with the September 29, 1982 hearing on the "exclusivity" policy.

After considering the testimony presented at the hearing held on September 29, 1982 and the written comments submitted to the record, FDA proposed in the **Federal Register** of April 22, 1985 (50 FR 15810) to change its exclusivity policy for the labeling of OTC drug products. In the **Federal Register** of May 1, 1986 (51 FR 16258), the agency published a final rule changing its labeling policy for stating the indications for use of OTC drug products. Under 21 CFR 330.1(c)(2), the label and labeling of OTC drug products are required to contain in a prominent and conspicuous location, either (1) the specific wording on indications for use established under an OTC drug monograph, which may appear within a boxed area designated "APPROVED USES"; (2) other wording describing such indications for use that meets the statutory prohibitions against false or misleading labeling, which shall neither appear within a boxed area nor be designated "APPROVED USES"; or (3) the approved monograph language on indications, which may appear within a boxed area designated "APPROVED USES", plus alternative language describing indications for use that is not false or misleading, which shall appear elsewhere in the labeling. All other OTC drug labeling required by a monograph or other regulation (*e.g.*, statement of identity, warnings, and directions) must appear in the specific wording established under the OTC drug monograph or other regulation where exact language has been established and identified by quotation marks, *e.g.*, 21 CFR 201.63 or 330.1(g). The proposed rule in this document is subject to the labeling provisions in § 330.1(c)(2).

5. Three comments requested the following indications as Category I labeling for products used for the treatment of diaper rash: "Promotes healing," "protects skin," "relieves chafing," "effective in sealing out wetness and germs," "promotes healing, protects and helps seal out wetness," "aids in the (temporary) relief of minor skin irritations due to (associated with) diaper rash," "for the (temporary) protection of minor skin irritations due to (associated with) diaper rash," "soothes minor skin irritations due to (associated with) diaper rash," "gives comfort to minor skin irritation(s) due to diaper rash," and "for symptoms of chafing, rubbing, and inflammation of infant's skin due to diaper rash." One comment requested that prevention of diaper rash be included as part of the Category I labeling indications for skin protectants, while the other comments suggested the following indications for products used for the prevention of diaper rash: "Aids (helps) in the prevention of diaper rash."

The agency has evaluated the comments' requests and determined that a general statement that informs consumers what these products do would be an appropriate indications statement. Accordingly, the agency is proposing in § 347.50(b)(5) the following statement for products containing a suitable skin protectant active ingredient: "Helps treat and prevent diaper rash." The agency believes that it would also be helpful to describe for consumers the protectant action of these ingredients in treating diaper rash. Therefore, the agency is also including the following information as part of the indications proposed in 347.50(b)(5) for these products in this tentative final monograph: "Protects" (select one of the following: "chafed skin" or "minor skin irritation") (select one of the following: "due to" or "associated with") "diaper rash and helps" (select one of the following: "protect from" or "seal out") "wetness." The comments' suggested indications "aids in the temporary relief of minor skin irritations due to (associated with) diaper rash" and "for the temporary protection of minor skin irritation due to (associated with) diaper rash" have been incorporated in the above indications statement. The agency believes that the indication "protects chafed skin" is more informative to consumers than the comments' suggestions of "protects skin" or just "protects."

In the tentative final monograph for OTC skin protectant drug products, the agency proposed to define a skin protectant as a drug which protects injured or exposed skin or mucous membrane surface from harmful or annoying stimuli. (See proposed § 347.3(a), 48 FR 6820 at 6832.) Wetness which contributes to diaper rash could be considered as "annoying stimuli" within this definition. Therefore, the claim "protects and helps seal out wetness" has been incorporated in the Category I indications for skin protectant ingredients for diaper rash. However, "sealing out germs" is a claim for which more testing is needed because there is a lack of evidence that skin protectant active ingredients perform this function.

Claims related to healing, e.g., "promotes healing," and wound healing aids are classified as Category III in the tentative final monograph for OTC skin protectant drug products (48 FR 6831) and in the tentative final monograph for OTC anorectal drug products (53 FR 30756 at 30765; August 15, 1988). The claim "promotes healing" has not been demonstrated in clinical studies for any ingredient contained in OTC diaper rash drug products. Data are needed to establish the effectiveness of any ingredient in diaper rash drug products for this claim. Therefore, this claim is not being included in the indications for diaper rash drug products at this time and is being classified in Category III.

Likewise, none of the proposed Category I ingredients for OTC diaper rash drug products have been shown to relieve inflammation of infants' skin due to diaper rash. Therefore, this claim also is not being included in the indications for diaper rash drug products at this time and is being classified in Category III.

The agency also stated in the tentative final monograph for OTC skin protectant drug products that it considered the terms "soothes" and "rubbing" to be cosmetic claims in the context of skin protectant products. (See 48 FR 6820 at 6828, comment 22.) Accordingly, these terms are not included in the indications for diaper rash drug products.

6. Two comments recommended the following warnings for products used for either the treatment or prevention of diaper rash: "for external use only," "avoid contact with the eyes," and "discontinue use if symptoms persist for more than seven days and consult a physician."

The agency agrees that the three warnings recommended by the comments are applicable to OTC diaper rash drug products. The warnings "for external use only" and "avoid contact with the eyes" are regularly included in the labeling for topical drug products and were proposed in § 347.50(c)(1) and (2) of the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6832). The comments' recommended warning regarding the time period for self-treatment is already covered by the warning proposed in 347.50(c)(3) of the tentative final monograph for OTC skin protectant drug products, which reads as follows: "If condition worsens or does not improve within 7 days, consult a doctor." In addition, the general warnings in § 330.1(g) will be required, i.e., "keep this and all drugs out of the reach of children," and "In case of accidental ingestion, seek professional assistance or contact a Poison Control Center immediately."

7. Two comments recommended the following directions for products used for either the treatment or prevention of diaper rash: "Apply liberally as often as necessary."

The agency agrees that the directions recommended by the comments are appropriate for skin protectant drug products used for the treatment and prevention of diaper rash. Most of the drug products marketed for the treatment or prevention of diaper rash contain one or more Category I active ingredients that were included in the tentative final monograph for OTC skin protectant drug products for which the agency proposed the directions: "Apply liberally as often as necessary." (See 48 FR 6833.) If there is a need for limiting the frequency or the amount of application of a specific ingredient for safety reasons, that limitation will be reflected in the directions for that specific ingredient.

Based on the Panel's statement that most diaper rash treatments help by protecting the skin, acting as a physical barrier to irritants, and absorbing or adsorbing moisture (47 FR 39436 at 39440) and based on the labeling of a number of currently marketed OTC diaper rash drug products, the agency believes that consumers should also be informed to "apply [the product] with each diaper change and especially at bedtime or anytime when exposure to wet diapers may be prolonged." In addition, based on information from standard texts (Refs. 1 through 5), the labeling of some currently marketed OTC diaper rash drug products (Refs. 6 and 7), numerous articles in the literature (Refs. 8 through 13), and the Miscellaneous External Panel's statement in its discussion on diaper rash that mild diaper rash responds to very frequent diaper changes and cleansing with water (47 FR 39440), the agency has determined that the following general statement would be useful in the directions for products labeled both for prevention and treatment of diaper rash: "Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry."

Based on numerous reports of toxic episodes resulting from inhalation of powders (see comment 28 below), and recommendations in the literature to shake the powder directly into the diaper or into the hand away from the child's face (Refs. 8 and 12), the agency believes the following information should be included in the directions for powder products: "Apply close to the body away from child's face. Carefully shake the powder into the diaper or into the hand and apply to diaper area." The agency tentatively concludes that these additional statements in the directions will provide consumers with more informative directions for safely and effectively using powder diaper rash drug products.

Based on the above, the agency is proposing the following directions for use in 347.50(d)(4) of this tentative final monograph: (i) *For all products.* "Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry. Apply" (select one of the following: "ointment," "cream," "powder," or "product") "liberally as often as necessary, with each diaper change, and especially at bedtime or anytime when exposure to wet diapers may be prolonged." (ii) *For powder products only.* "Apply powder close to the body away from child's face. Carefully shake the powder into the diaper or into the hand and apply to diaper area."

The agency also notes that should the final monograph provide for a diaper rash drug product containing a skin protectant active ingredient and Category I topical active ingredient(s) from another class, e.g., an antimicrobial, antifungal, or external analgesic, with a specific time interval or specified quantity for application, then the labeled frequency of application or the amount to be applied of the combination product would not be "liberally as often as necessary." In such situations, the directions for applying the product would not be allowed to exceed the maximum limit established for any ingredient in the product.

References

(1) Smith, G.H., "Diaper Rash and Prickly Heat Products," in "Handbook of Nonprescription Drugs," 7th Ed., American Pharmaceutical Association, Washington, pp. 605–614, 1982.

(2) Weston, W.L., "Practical Pediatric Dermatology," 1st Ed., Little, Brown and Co., Boston, pp. 51–53, 1979.

(3) Weinberg, S., and R.A. Hoekelman, "Pediatric Dermatology for the Primary Care Practitioner," 1st Ed., McGraw-Hill, New York, p. 121, 1979.

(4) Barnett, G., "Baby Toiletries," *in* "Cosmetics Science and Technology," 2d Ed., Wiley-Interscience, New York, pp. 121–135, 1972.

(5) Zimmerman, D.R., "Diaper-Rash Medications," *in* "The Essential Guide to Nonprescription Drugs," 1st Ed., Harper and Row, New York, pp. 228–237, 1983.

(6) Huff, B.B., editor, "Physicians Desk Reference for Nonprescription Drugs," 10th Ed., Medical Economics Co., Inc., Oradell, NJ, pp. 573–574, 682, 1989.

(7) Current labeling for Johnson and Johnson Baby Powder, in OTC Volume 06DRSTFM, Docket No. 78N–021D, Dockets Management Branch.

(8) Brown, M.S., "Over-the-Counter Drugs for Skin Disorders Part 3: Aids for Heat and Diaper Rash," Nurse Practitioner, July–August: 28–30 and 36, 1977.

(9) Sadik, F., "OTC Products for Diaper Rash and Prickly Heat," Journal of American Pharmaceutical Association, 1:19–24, 1970.

(10) Williams, M.L.K., "How I Treat Diaper Rashes," Medical Times, 108:50–53, 1980.

(11) Schanzer, M.C., and J.K. Wilkin, "Diaper Dermatitis," American Family Physician, 25:127–132, 1982.

(12) Gossel, T.A., "Diaper Dermatitis," U. S. Pharmacist, September: 34–40, 1984.

(13) Leyden, J.J., "Diaper Dermatitis," Dermatologic Clinics, 4:23–28, 1986.

C. Comment on Previously Classified Skin Protectant Active Ingredients

8. One comment noted that the reopenings of the administrative record to include the Miscellaneous External Panel's findings on drug products used for diaper rash treatment did not include any Category I ingredients or labeling for this drug category. The comment recommended that those Category I skin protectant active ingredients that ameliorate skin irritation should be listed as Category I agents for diaper rash. The comment asserted that the Miscellaneous External Panel believed that the use of adsorbents, absorbents, astringents, demulcents, emollients, lubricants, and wound healing aids provide mechanical or physical protection which may prevent further irritation associated with diaper rash (47 FR 39436 at 39439).

The agency agrees with the comment that the physical or mechanical protection afforded by skin protectant ingredients is useful in the prevention and treatment of diaper rash. In the advance notice of proposed rulemaking for OTC anorectal drug products (45 FR 35576; May 27, 1980), the Advisory Review Panel on OTC Hemorrhoidal Drug Products (Hemorrhoidal Panel) stated its conclusion that protectants alone or in combination are of therapeutic value by providing a physical barrier that prevents irritation of anorectal tissue. That Panel further stated its belief in the concept of protectants providing a physical barrier over anorectal tissue and preventing further insult, and that the barrier effect of protectants is supported by data indicating that infant perianal skin is afforded significant protection against diaper wetness by the application of a continuous film of petrolatum to the skin in the diaper area (45 FR 35576 at 35627). The agency agrees with the Panel that skin protectants that provide a protective barrier would be useful in either preventing diaper rash or preventing further irritation in the case of an existing diaper rash. The agency also believes that because moisture plays a large part in the development of diaper rash irritation, skin protectant ingredients that absorb or adsorb moisture offer a rational approach to both the prevention or treatment of diaper rash.

The Topical Analgesic Panel, which evaluated skin protectant active ingredients, recommended the following as Category I skin protectant ingredients for use on adults, children, and infants, without any age restrictions: allantoin, calamine, cocoa butter, corn starch, dimethicone, kaolin, petrolatum, sodium bicarbonate, zinc carbonate, and zinc oxide (43 FR 34628 at 34634 through 34642; August 4, 1978). In the tentative final monograph for OTC skin protectant drug products, the agency tentatively deleted corn starch from the skin protectant monograph until diaper rash products were reviewed (48 FR 6820 at 6828). The agency's comments on the use of corn starch in the prevention and treatment of diaper rash appear in comment 18 below. Sodium bicarbonate was transferred by the agency to the external analgesic rulemaking for its antipruritic label claims (48 FR 6830). However, the diaper rash uses of sodium bicarbonate are now being considered in the skin protectant rulemaking and are discussed in comment 27 below.

Because the Topical Analgesic Panel did not specifically review skin protectant ingredients for their use in the prevention or treatment of diaper rash, the agency has evaluated those Category I ingredients that have been used in diaper rash drug products. Of the ingredients discussed above, allantoin, calamine, dimethicone, kaolin, petrolatum, and zinc oxide have an extensive marketing history for the prevention or treatment of diaper rash (Refs. 1 through 4). The agency is not aware of any marketing history for the ingredients cocoa butter or zinc carbonate in products used for diaper rash. Therefore, the agency is proposing those two ingredients as Category III for this specific skin protectant use.

The Topical Analgesic Panel also recommended that four Category I skin protectant ingredients be restricted in their use on children. The Panel recommended the warning "Do not use on children under 2 years of age without consulting a physician," for shark liver oil and zinc acetate (43 FR 34628 at 34640 and 34641). For the ingredients aluminum hydroxide gel and glycerin, the Panel recommended the warning "Do not use on children under 6 months of age without consulting a physician," (43 FR 34634 and 34638). The agency included the warnings for the ingredients aluminum hydroxide gel, glycerin, and zinc acetate in the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6833) and deferred a decision on limiting the use of shark liver oil as a skin protectant for the treatment of diaper rash, pending completion of its evaluation of diaper rash products (48 FR 6825). The agency's recommendations on the use of shark liver oil for the treatment of diaper rash are discussed below in this comment.

No data have been submitted to the agency on the use of aluminum hydroxide gel or zinc acetate for the prevention or treatment of diaper rash. In addition, the agency is not aware of any safety data supporting the use of these ingredients on infants. Accordingly, these ingredients are not included as Category I diaper rash ingredients and are classified in Category III.

The Topical Analgesic Panel recommended that 20 to 45 percent glycerin not be used on children under 6 months of age. The agency has received no data in this rulemaking, and is not aware of any data, supporting the safe use of glycerin at this concentration on children under 6 months of age. Therefore, the agency is classifying 20 to 45 percent glycerin in Category III for safety for use as a skin protectant in the prevention or treatment of diaper rash.

The agency received one submission for a combination diaper rash product containing an antimicrobial ingredient (0.1 percent methylbenzethonium chloride), 17.5 percent petrolatum, and 12 percent glycerin as active ingredients (Ref. 5). The data included a study by Niedelman and Bleier using the product for the treatment of diaper rash (Ref. 6). As part of the study, a patch test was performed using the product on 50 infants and children. The infants were divided into three groups and ointment was applied to the back or arm and covered with a half-inch square gauze covered with wax paper and held in place by adhesive tape. In the first group the patch was removed after 24 hours, in the second group after 48 hours, and in the remaining group after 72 hours. The patch test yielded no evidence of sensitivity to the ointment.

In another study by Bleier and Niedelman, 90 infants were studied to determine the safety and effectiveness of the above antimicrobial ointment in the treatment of diaper rash (Ref. 7). The infants, diagnosed as having diaper rash of varying degrees of severity (mild to severe), were divided into two groups. Fifty-eight infants received the antimicrobial ointment and a control group of 32 infants received the base ointment containing 12 percent glycerin and petrolatum. During the treatment study period the authors noted no systemic toxicity, local irritation, or primary or secondary sensitivity in either group.

Lipschutz and Fischer reported similar observations in their study using the same ointment on 100 infants studied over a 3-month period (Ref. 8). Alternate infants were treated with the antimicrobial ointment or the base

containing 12 percent glycerin and petrolatum. The ointment was applied after each diaper change and upon retiring for the night (an average of seven times a day) and no demonstrable toxicity or allergenicity of the ointment was noted. However, because the ages of the infants in the above studies were not specified, no conclusions on the safety of the use of 12 percent glycerin on infants under 6 months of age can be made.

Further, the Panel recommended glycerin at a concentration of 20 to 45 percent as an effective Category I skin protectant (43 FR 34628 at 34648), and the data included in the submission do not demonstrate the effectiveness of the lower concentration of glycerin for the treatment or prevention of diaper rash.

The studies by Bleier and Niedelman (Ref. 7) and Lipschutz and Fischer (Ref. 8) were designed to demonstrate the contribution of the antimicrobial ingredient to the product's effectiveness. No conclusions concerning glycerin's contribution to the effectiveness of the product can be made because glycerin is in combination with petrolatum, another Category I skin protectant ingredient, and both ingredients are present in the placebo and the tested product. Although Niedelman and Bleier (Ref. 6) studied the effectiveness of the Product on 107 infants with diaper rash, they used the complete formulation containing petrolatum, 12 percent glycerin, and the antimicrobial ingredient, and no controls were used. Accordingly, 12 percent glycerin is classified in Category III for safety and effectiveness for use in the treatment and prevention of diaper rash.

In response to the advance notice of proposed rulemaking for OTC skin protectant drug products, the agency received a comment (Ref. 9) opposing the Topical Analgesic Panel's recommendation against using shark liver oil on children under two years of age. The comment argued that the Panel gave no reason for limiting the use of this ingredient on children under 2 and failed to mention that a product containing shark liver oil specifically labeled for use for diaper rash was submitted (Ref. 10). The submission contains a summary of a diaper rash study conducted by Minsky. The study compared an ointment containing 2,000 units of live yeast cell derivative (LYCD) and 3 percent shark liver oil to an undescribed placebo on 54 newborns with peri-rectal diaper rash. All cases had erythema plus either vesiculation, papulation, or excoriation. The infants were divided into a test group of 29 infants treated with the LYCD-shark liver oil combination and a control group of 25 infants treated with the placebo. The comment also cited a study by Grayzel, Heimer, and Grayzel on the value of cod liver oil in the treatment of various dermatoses in infants and adults in support of the safe topical use of shark liver oil on children under the age of two (Ref. 11).

The agency has reviewed the submission (Ref. 10) and the studies mentioned above and determined that the data are insufficient to demonstrate the safe topical use of shark liver oil on children under 2 years of age. In the Minsky study (Ref. 10), 86 percent of the infants in the test group were cured or improved as opposed to 76 percent in the control group. No adverse reactions to either treatment were noted. The lack of any adverse reactions in the 29 infants in the test group is not considered sufficient data to support the safe use of this ingredient for the treatment of diaper rash in children under 2 years of age.

The study by Grayzel, Heimer, and Grayzel (Ref. 11) investigated the effects of cod liver oil in an ointment or lotion base on various dermatoses in 295 infants and children and 56 adults. During the course of the study, no evidence of sensitivity or dermatitis attributable to the ointment or lotion was noted. However, because the amount of cod liver oil in the preparations used in the study is not specified, no comparison to shark liver oil can be made. Further, while cod liver oil and shark liver oil are both sources of vitamins A and D (Refs. 12 and 13), they do not contain the same amounts of either vitamin and, therefore, cannot be considered interchangeable. Accordingly, shark liver oil is classified in Category III for safety for use in the treatment and prevention of diaper rash. The agency's comments on the use of cod liver oil for the prevention or treatment of diaper rash appear in comment 14 below. The agency's comments on the use of vitamins A and D for diaper rash appear in comment 29 below.

Based on the discussion above, the agency is proposing that the following skin protectant ingredients be classified as Category I for the prevention and treatment of diaper rash: allantoin, calamine, dimethicone, kaolin, petrolatum, white petrolatum, and zinc oxide. The agency is proposing that aluminum hydroxide gel, cocoa butter, glycerin, shark liver oil, zinc acetate, and zinc carbonate be classified as Category III for this use.

References

(1) Smith, G.H., "Diaper Rash and Prickly Heat," in "Handbook of Nonprescription Drugs," 6th Ed., American Pharmaceutical Association, Washington, pp. 427–429, 1979.

(2) "Kastrup, E.K., editor, "Topical Diaper Rash Products," in "Facts and Comparisons," J. B. Lippincott Co., St. Louis, p. 563, August 1987.

(3) Brown, M.S., "Over-the-Counter Drugs for Skin Disorders Part 3: Aids for Heat and Diaper Rash," Nurse Practitioner, 2:28–30, 36, and 41, 1977.

(4) OTC Volumes 160021, 160027, 160040, 160041, 160053, 160077, 160150, 160242, 160245, and 160421.

(5) OTC Volume 160243.

(6) Niedelman, M.L., and A. Bleier, "Ammonia Dermatitis: Treatment with Diaperene Chloride Ointment," Journal of Pediatrics, 37:762–764, 1950.

(7) Bleier, A., and M.L. Niedelman, "Ammonia Dermatitis: Comparative Study of Diaperene® Chloride Ointment," Archives of Pediatrics, 69:445–449, 1952.

(8) Lipschutz, A., and C. Fischer, "Methylbenzethonium Chloride in the Care of Skin of Infants and Children," American Journal of Diseases of Children, 89:596–598, 1955.

(9) Comment No. C00006, Docket No. 77N–0021, Dockets Management Branch.

(10) OTC Volume 060113.

(11) Grayzel, H.G., C.B. Heimer, and R.W. Grayzel, "The Value of a Cod Liver Oil Ointment and Cod Liver Oil Lotion in the Treatment of Dermatoses," New York State Medical Journal, October: 2233–2237, 1953.

(12) "The United States Pharmacopeia XXII—The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 344–345, 1989.

(13) Wade, A., "Martindale. The Extra Pharmacopoeia," 27th Ed., The Pharmaceutical Press, London, pp. 1097–1098, 1978.

D. Comment on Aldioxa.

9. A submission to the Miscellaneous External Panel (Ref. 1) requested Category I status for a product containing 0.2 percent aldioxa (formerly aluminum dihydroxy allantoinate) for the prevention of diaper rash. Although this ingredient is not included in the currently marketed product (Ref. 2), the original submission was reviewed for background information by the Panel in preparing its statement on diaper rash drug products. The submission included reports on oral toxicity studies of aldioxa in mice, a report on the topical sensitizing and irritating potential of aldioxa in guinea pigs, and reports on the safety of the ingredient in infants and children with varying degrees of dermatitis of the buttocks.

Aldioxa is an aluminum salt of the Category I skin protectant allantoin; it is formed by reacting soluble salts of aluminum with allantoin. The resulting compound has astringent properties

attributable to the aluminum in its chemical composition (Ref. 3). The Topical Analgesic Panel, in discussing the safety of allantoin in its report on OTC skin protectant drug products, cited animal sensitization studies and acute oral toxicity studies in rats in which aldioxa was tested (43 FR 34628 at 34632). Based in part on these studies, the Panel concluded that allantoin is safe in OTC topical drug products (43 FR 34633). However, the Panel did not specifically classify aldioxa as a Category I skin protectant, and the data did not address the safety of using aldioxa on infants' skin under conditions such as those present in the diaper area, e.g., increased moisture and occlusion.

One of the reports included in the submission (Ref. 4) is a clinical evaluation by a practicing physician of a talcum powder containing 0.2 percent aldioxa, magnesium stearate, and silicones. Over a 6-month period, 100 infants and children with weeping eczematous rashes, such as heat rash, diaper rash, and similar inflammations, were treated with the powder. The physician concluded that the powder was nonirritating, nontoxic, nonsensitizing, aided in the prevention of diaper rash, and alleviated and prevented irritation due to chafing. However, the report did not provide any details as to the number of diaper rash cases treated, the method of treatment, and the individual responses to treatment with the aldioxa-containing talcum powder. Further, no evaluation of the contribution of the aldioxa to the effectiveness of the product can be made because the evaluation did not include a talc placebo.

In another clinical evaluation by the same physician (Ref. 5), 70 infants with diaper rash and other weeping eczematous rashes were treated daily with a cream containing 0.75 percent aldioxa. No sensitizing or allergic reactions were noted, and in all cases the irritation cleared completely. The report did not provide any details on the number of diaper rash cases treated, method of treatment, or length of treatment.

A clinical evaluation by another physician of the use of a cream containing 0.75 percent aldioxa in a glyceryl monostearate base on 116 infants is included in the submission (Ref. 6). Seventy of the infants showed no sign of irritation in the diaper area at the time of admission or subsequently during the evaluation. Of the 46 infants who showed some irritation at time of admission, 30 were cured, 6 were not observed for a sufficient period of time, and 10 showed no noticeable change. This report also did not provide any details.

The reports discussed above do not provide sufficient detail to support a Category I classification for 0.2 to 0.75 percent aldioxa used for the prevention or treatment of diaper rash. Accordingly, the agency is classifying 0.2 to 0.75 percent aldioxa in Category III for safety and effectiveness for the prevention or treatment of diaper rash.

REFERENCES

(1) OTC Volume 160357.

(2) Letter from B. Leiro, Stiefel Laboratories, Inc., to L. Geismar, FDA, dated October 23, 1986, in OTC Volume 06DRSTFM, Docket No. 78N–021D, Dockets Management Branch.

(3) Mecca, S.B., "Allantoin and the Newer Allantoinates," located at p. 148 in OTC Volume 160357.

(4) Letter containing clinical evaluation of talc, from F.X. Thomas, to Schuylkill Chemical Co., not dated, located at p. 135 in OTC Volume 160357.

(5) Letter from F.X. Thomas, to Schuylkill Chemical Co., not dated, located at p. 137 in OTC Volume 160357.

(6) High, R., "Clinical Evaluation of a Cream Containing 0.75% Aluminum Dihydroxy Allantoinate in a Glyceryl Monostearate Base for the Treatment of 116 Infants With Varying Degrees of Dermatitis of the Buttocks," summary located at p. 138 in OTC Volume 160357.

E. Comment on Aluminum Acetate

10. One manufacturer submitted data to the Miscellaneous External Panel for two products (a cream and a lotion) containing aluminum acetate as the claimed active ingredient (Ref. 1). The manufacturer stated that the formulation includes the components of a modified Burow's solution and that the products are used to restore the skin to its normal protective acid pH. The labeling states that the products "aid in treatment of diaper rash," and the manufacturer requested that the agency place aluminum acetate in Category I for various indications, including "as an aid in the treatment of diaper rash."

The manufacturer subsequently submitted a comment (Ref. 2) for another product containing aluminum acetate used as a wet dressing and requested that the Panel's recommended indications for aluminum acetate solution in § 348.50(b)(4) be revised to include "a soothing wet dressing for relief of skin irritations caused by conditions such as * * * diaper rash * * *." The comment did not provide any data regarding the use of aluminum acetate for the treatment of diaper rash, but did include a copy of the transcript of the November 7, 1980 meeting of the Miscellaneous External Panel which contained the manufacturer's presentation on the ingredient in solution dosage form for use as a compress.

In its statements on OTC astringent drug products (47 FR 39412 at 39425 and 39436 at 39444; September 7, 1982), the Miscellaneous External Panel recommended that the use of astringents be referred to both the external analgesic and skin protectant rulemakings. The agency's proposals concerning the use of external analgesic ingredients for the treatment or prevention of diaper rash appear elsewhere in this issue of the Federal Register. Based on the available information, the agency is proposing that any products labeled for the prevention or treatment of diaper rash should not contain any external analgesic ingredients. Based on the manufacturer's claim that aluminum acetate restores the skin to its normal protective acid pH, the agency is considering this ingredient when used in OTC diaper rash drug products to be a skin protectant (see definition of a skin protectant in § 347.3(a) of the tentative final monograph for OTC skin protectant drug products; 48 FR 6820 at 6832) and thus is addressing its use for the treatment of diaper rash in this document. Other uses of aluminum acetate will be addressed in subsequent publications in the Federal Register.

In the Miscellaneous External Panel's report on the skin protectant uses of astringent drug products, the Panel recommended that aluminum acetate solution be Category I as an astringent (47 FR 39436 at 39444). However, the Panel did not include the treatment of diaper rash among its proposed indications for this ingredient. The agency is aware of the recommended use of aluminum acetate solution (Burow's solution) in the treatment of severe diaper rash characterized by acute inflammation with oozing or crusting and in candidal diaper rash (Refs. 3, 4, and 5). However, the agency believes that these severe forms of diaper rash are not amenable to OTC treatment and should be treated by a physician. In addition, the agency is not aware of any data supporting the safe and effective use of aluminum acetate solution in the treatment of simple diaper rash.

The submission (Ref. 1) for the cream and lotion products included information regarding the composition of the skin's "acid mantle" and its importance to the skin's barrier functions (Refs. 6, 7, and 8). However, the submission did not contain any data showing the effects of aluminum acetate

cream or lotion in restoring the "acid mantle" or a normal pH to skin irritated by a diaper rash or any data concerning the safe and effective use of aluminum acetate in any dosage form for the treatment of diaper rash. Data and information are needed to show that aluminum acetate restores the skin in the diaper area to its normal protective acid pH, and that the drug has a role in the treatment or prevention of diaper rash. At the November 7, 1980 meeting of the Miscellaneous External Panel, Dr. Leyden discussed a study in which wet dressings containing aluminum acetate were used on six volunteers with induced poison ivy. The Panel voted to classify Burow's (aluminum acetate) solution in Category I for use as an astringent wet dressing based on years of experience and the results of the study; however, use of the wet dressing for diaper rash was not discussed.

Accordingly, the agency concludes that there are insufficient data available to classify aluminum acetate as safe or effective for the OTC treatment of diaper rash and classifies the ingredient as Category III.

References

(1) OTC Volume 160038.

(2) Comment No. C00038, Docket No. 78N–0301, Dockets Management Branch.

(3) Schanzer, M.C., and J.K. Wilkin, "Diaper Dermatitis," American Family Physician, 25:127–132, 1982.

(4) Williams, M.L.K., "How I Treat Diaper Rashes," Medical Times, 108:50–53, 1980.

(5) Smith, G.H., "Diaper Rash and Prickly Heat Products," in "Handbook of Nonprescription Drugs," 8th Ed., American Pharmaceutical Association, Washington, pp. 643–653, 1986.

(6) Gleeson-White, M.H., "The Skin Flora and the Staphylococcus," in "Progress in the Biological Sciences in Relation to Dermatology," edited by A. Rook, University Press, Cambridge, pp. 155–157, 1960.

(7) Hjorth, N., and S. Fregert, "Contact Dermatitis," in "Textbook of Dermatology," edited by A. Rook, D. Wilkinson, and F. Ebling, F.A. Davis Co., Philadelphia, pp. 238–240, 1968.

(8) Montagna, W., "The Structure and Function of Skin," 2d Ed., Academic Press, New York and London, p. 100, 1962.

F. Comment on Bismuth Subnitrate

11. Three submissions to the Miscellaneous External Panel (Ref. 1) from the same manufacturer included data to support the safe and effective use of a product containing bismuth subnitrate (5.8 percent), zinc oxide, and Peru balsam oil as active ingredients for the treatment of diaper rash. Based on the product's current labeling (Ref. 2), the active ingredients of the products are bismuth subnitrate and zinc oxide. (Peru balsam oil is discussed in comment 25 below.)

A submission from another manufacturer (Ref. 3) included information on a combination product containing nine active ingredients, one of which was bismuth subnitrate. The submission did not include any specific information on the use of bismuth subnitrate for the treatment of diaper rash. Based on the product's current labeling (Ref. 4), the product has been reformulated and no longer contains bismuth subnitrate.

The agency has reviewed the data included in the submissions (Refs. 1 and 3) and concludes that they are not adequate to support the safety and effectiveness of bismuth subnitrate for the treatment of diaper rash. One of the submissions described a patch test that was performed on 200 subjects to determine the presence of primary irritation or allergenicity. The test sites were thoroughly cleansed with ether and the product (containing zinc oxide, bismuth subnitrate, and balsam peru) was applied to the skin and covered with a patch. Waterproof tape was then applied to the patch to assure good contact with the skin, and the patch remained on the skin for 48 hours. The test sites were observed and reactions noted after 48 hours and again after 20 minutes to rule out any mechanical reactions. Fifty of the 200 subjects were then retested to rule out any allergic responses. None of the subjects showed any primary irritation or allergic responses. Based on the results of the test, the investigator concluded that the product is not irritating to the skin when applied topically. However, the patch test does not address the use of this ingredient on macerated infant skin as might be found in the case of diaper rash.

An effectiveness study included in the same submission (Ref. 5) evaluated the use of the product containing bismuth subnitrate, zinc oxide, and balsam peru on 558 infants with perianal dermatitis and/or diaper dermatitis. Of the 558 infants tested, 537 infants showed a clearing of their dermatitis; 21 infants showed no clearing. The amount of data presented is very limited. No information was provided on the severity of the rashes of the infants, frequency of application of the product, or length of treatment. Further, the product tested was a combination product. None of the individual components were studied, and there was no vehicle control; thus, it is impossible to assess the effect that bismuth subnitrate contributed to the results observed.

The Topical Analgesic Panel evaluated the use of bismuth subnitrate for use as an OTC skin protectant ingredient and concluded that the ingredient was not safe or effective for this use (43 FR 34628 at 34642). In discussing the safety of this ingredient, the Panel cited reports of fatalities in infants due to oral ingestion of bismuth subnitrate and classified the ingredient in Category II (43 FR 34642). The agency concurred with the Panel's recommendation in the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6831).

The use of bismuth subnitrate as a skin protectant was also evaluated by the Hemorrhoidal Panel (45 FR 35576 at 35636). In discussing the safety of this ingredient, that Panel cited human and animal studies demonstrating absorption of bismuth salts through local application to open surfaces. The Panel concluded that the lesions and ulcerations caused by local application of the ingredient were due to metallic bismuth and that bismuth toxicity can be caused by bismuth subnitrate (45 FR 35637). Of greater concern to the Panel was the possibility of nitrite toxicity due to the conversion of nitrate to nitrite in the presence of bacteria normally found in the colon and rectum. The Panel stated that the signs and symptoms of nitrite intoxication are vomiting, convulsions, dizziness, sleepiness, methemoglobinemia, and cardiac collapse. The Panel concluded that because of the rapid absorption of nitrites across mucous membranes, bismuth subnitrate is not safe for use as an OTC anorectal drug product (45 FR 35637). The Panel further concluded that there was no evidence that bismuth subnitrate is more effective than other protectant ingredients which are not associated with a safety problem and classified it in Category II for safety and effectiveness.

Because the studies discussed above do not demonstrate the safety of bismuth subnitrate for use in diaper rash, the agency tentatively concludes that bismuth subnitrate is not safe for OTC use for the treatment of diaper rash. Further, because the only clinical study submitted to support effectiveness involved a combination product, the contribution of bismuth subnitrate to the effectiveness of the product has not been demonstrated. Accordingly, the agency is classifying bismuth subnitrate in Category II for safety and effectiveness for the treatment of diaper rash.

References

(1) OTC Volumes 160041, 160088, and 160421.

(2) Labeling for product Balmex, sent by Macsil, Inc., to FDA, Division of OTC Drug Evaluation, postmarked October 24, 1986, in

OTC Volume 06DRSTFM, Docket No. 78N-021D, Dockets Management Branch.

(3) OTC Volume 160040.

(4) Letter from J.A. Devaney, The Mentholatum Co., Inc., to L. Geismar, FDA, October 23, 1986, in OTC Volume 06DRSTFM, Docket No. 78N-021D, Dockets Management Branch.

(5) Letter containing evaluation of Balmex Baby Cream from G.Y. Elson to M. Waxman, Macsil, Inc., dated October 1956, in OTC Volume 160041.

G. Comment on Borax and Boric Acid

12. One comment requested that borax and boric acid be classified as "inactive" ingredients in diaper rash drug products. The comment contended that borax and boric acid in diaper rash drug products were inactive as defined in 21 CFR 210.3(b) (7) and (8). The comment stated that it had examined the OTC volumes (Refs. 1 through 10) submitted to the Panel for products containing boric acid and/or borax and these submissions did not disclose any claims for their use as active ingredients. The comment added that these ingredients are not active when used as buffering agents (Refs. 1 and 10), preservatives, or stabilizers (in emulsions) because their role is not to treat diaper rash. The comment noted that the Panel stated at 47 FR 39416 that it did not review any individual ingredients as used in OTC diaper rash drug products. The comment asked whether these ingredients can continue to be used as pharmaceutical necessities in diaper rash drug products.

The agency has reviewed the submissions referred to by the comment and determined that the labeling and information contained in some of them represent boric acid as an active ingredient in four products, three of which were labeled for diaper rash use (Refs. 3, 4, 5, and 10). In evaluating the current formulations of these products, the agency has determined that three of the products have been reformulated to delete the boric acid and the fourth product has been discontinued (Refs. 11, 12, and 13). The agency has surveyed products currently available in the marketplace and identified one additional ointment that contains 5 percent boric acid and is labeled for use in diaper rash (Ref. 14). Boric acid is considered an active ingredient in this product.

A number of OTC advisory review panels have evaluated the safety of boric acid and have found it to be unsafe for use in OTC anorectal, skin protectant, dandruff and seborrheic dermatitis, oral health care, and vaginal (at greater than 1 percent concentration) drug products. Based on these panels' classifications, the agency considers boric acid to be Category II (not generally recognized as safe) as an active ingredient in diaper rash drug products.

The agency is not aware of boric acid or borax being used or of the need to use either as an inactive ingredient to buffer, preserve, or stabilize any OTC diaper rash drug product. The regulations for products regulated by OTC drug monographs state that "the product contains only suitable inactive ingredients which are safe in the amounts administered * * *." (See 21 CFR 330.1(e).) The agency is not aware of any evidence establishing that boric acid or borax is a suitable inactive ingredient for use in OTC diaper rash drug products.

References

(1) OTC Volume 160022.
(2) OTC Volume 160024.
(3) OTC Volume 160040.
(4) OTC Volume 160077.
(5) OTC Volume 160091.
(6) OTC Volume 160093.
(7) OTC Volume 160140.
(8) OTC Volume 160230.
(9) OTC Volume 160233.
(10) OTC Volume 160236.
(11) Comment No. RPT, Docket No. 80N-0476, Dockets Management Branch.
(12) Letter from J.A. Devaney, The Mentholatum Co., Inc., to L. Geismar, FDA, dated October 23, 1986, in OTC Volume 06DRSTFM, Docket No. 78N-021D, Dockets Management Branch.
(13) Letter from A.D. Marcus, Bristol-Myers Products, to Dockets Management Branch, FDA, dated March 11, 1987, coded LET017, Docket No. 78N-021D, Dockets Management Branch.
(14) Smith, G.H., "Diaper Rash and Prickly Heat Products," in "Handbook of Nonprescription Drugs," 8th Ed., American Pharmaceutical Association, Washington, p. 651, 1986.

H. Comment on Casein

13. One manufacturer submitted data to the Miscellaneous External Panel for a combination product for which it listed four active ingredients, one of which was casein (calcium caseinate powder) (Ref. 1). The product was labeled for the treatment and prevention of diaper rash. The submission included a study by Grossman (Ref. 2) who described the product as "an antienzymatic and antibacterial ointment * * * with a casein competitive substrate * * *." However, neither Grossman nor the manufacturer provided any additional information concerning casein (calcium caseinate) in the combination drug product.

Subsequently, the manufacturer submitted the current labeling for the product, and this labeling did not include casein (calcium caseinate powder) as an active ingredient (Ref. 3). Because the agency is not aware of any use of this ingredient as an active ingredient in diaper rash drug products, casein (calcium caseinate) is not being classified in this rulemaking.

References

(1) OTC Volume 160245.
(2) Grossman, L., "A New Specific Treatment for Perianal Dermatitis," Archives of Pediatrics, 71:173-179, 1954.
(3) Letter from C.E. Calcagni, Sterling Drug Inc., to L. Geismar, FDA, dated December 30, 1986, in OTC Volume 06DRSTFM, Docket No. 78N-021D, Dockets Management Branch.

I. Comments on Cod Liver Oil

14. Two comments requested Category I status for cod liver oil used for the treatment and prevention of diaper rash. The comments pointed out that cod liver oil has skin protectant properties and is recognized for its barrier-like action, water insolubility, and emollience. One of the comments (Ref. 1) cited data previously submitted to the Miscellaneous External Panel regarding its combination product containing 13.56 percent cod liver oil and 40 percent zinc oxide in a petrolatum-lanolin vehicle (Ref. 2); submitted a report from a clinical study on this product (Ref. 3) that was referenced in its previous submission (Ref. 2); and requested that its combination product as well as the individual active ingredients and quantities contained therein be classified as Category I for the treatment and prevention of diaper rash. Another drug manufacturer also made a submission on a marketed combination product containing 5 percent cod liver oil (containing natural vitamins A and D), 20 percent zinc oxide, and 0.1 percent methylbenzethonium chloride in a calcium caseinate powder vehicle (Ref. 4). The comments and submissions (Refs. 1 through 4) also included published and unpublished clinical study data regarding the treatment and/or prevention of diaper rash in newborn infants and dermatoses in incontinent, chronically-ill patients.

Cod liver oil was not previously categorized for use as an OTC skin protectant because the agency deferred review of this ingredient to its evaluation of diaper rash drug products. (See the notice of proposed rulemaking for OTC skin protectant drug products, 48 FR 6820 at 6825 comment 12.)

The agency has evaluated the submitted data. In a study by Grayzel, Heimer, and Grayzel (Ref. 5), three combination products containing cod liver oil (concentrations not specified) were tested for four general groups of dermatologic conditions in infants,

children, and adults. A total of 295 infants and children and 56 adults was studied. One subgroup (that included 215 infants and children) having a variety of significant contact dermatitis (as a result of repeated and continuous contact with external irritants such as diarrheal stools, soaked diapers, or ammoniacal urine) was treated with a cod liver oil ointment. Results were rated either as good (indicating return of skin condition to practically normal) or fair (indicating a significant amelioration of skin condition) only if an immediate favorable response occurred within 24 hours, with a maximum effect within 48 hours. The results were good in 164 cases (76 percent), fair in 44 patients (21 percent), and there was no change in skin condition in 7 cases (3 percent). For 153 infants under 1 year of age, the results were good for 111 (72.5 percent), fair for 36 (23.5 percent), and unchanged for 6 (4 percent). The authors concluded that "cod liver oil ointment and cod liver oil lotion offer good topical applications for the treatment of a variety of skin disorders and wounds. They are safe, harmless, * * * may be used without fear of skin sensitivity * * *." (See Ref. 5 page 2237.)

A clinical study (Ref. 3) conducted using a crossover design involved treatment of diaper rash in 45 infants with a product containing cod liver oil in addition to other protectants. The infants had basically untreated diaper rash of at least 12 hours duration immediately prior to admission to the study. Twenty infants had the product applied to the left side but not the right; 25 infants were treated on the right side, but not the left. The product was applied at the beginning of the study and at each diaper change for approximately 24 hours. The severity of the diaper rash was graded prior to application of the product and at the completion of treatment. The investigator concluded that "on the average the treated side was better than the untreated side." Further, no adverse reactions were noted. However, the study does not serve to demonstrate the effect of the individual ingredients in the formulation.

While none of the clinical study data (Refs. 1 through 4) included vehicle controls or showed the contribution of cod liver oil alone, the long history of clinical use of cod liver oil in ointments support its safety and effectiveness as a skin protectant ingredient for use in diaper rash drug products (Refs. 5 through 8). Cod liver oil, when used in combination with other protectants, provides a physical barrier that protects the skin and thus helps to prevent irritation of the diaper area. Lee (Ref. 6) addressed formulations of cod liver oil as follows:

> * * * cod-liver oil alone is not quite sufficient and an added component containing astringent and oligo-dynamic qualities is desirable. * * * Many ointments obtained by simple admixture of ingredients have the defect * * * of melting quickly at body temperature, thus releasing the unpleasant smell of cod-liver oil and soaking through the bandage * * * a cod-liver oil-zinc paste preparation * * * produced the desired effect with a retention of its consistency at body temperature. (Quoted material found on last unnumbered page.)

The agency has surveyed the marketplace and determined that cod liver oil is marketed in a number of products with diaper rash claims (Refs. 8 and 9). The Handbook of Nonprescription Drugs (Ref. 8) identifies four products that contain cod liver oil. As best as the agency can ascertain, cod liver oil is being marketed in diaper rash drug products only in combination with other ingredients, such as lanolin and petrolatum. Based on the various submissions and the Handbook of Nonprescription Drugs, the agency has determined that these products are available at concentrations of 5 to 13.56 percent cod liver oil and that all such products contain more than one skin protectant ingredient for use in the treatment and prevention of diaper rash.

In the rulemaking for OTC anorectal drug products, the Hemorrhoidal Panel classified cod liver oil (50 percent or greater per dosage unit) in Category I for use as a protectant (anorectal agent) (May 27, 1980; 45 FR 35630). The Panel stated that an extensive review of the literature on cod liver oil reveals no adverse effects when applied topically as a protectant. The Panel concluded that the effectiveness of cod liver oil as a protectant is due to its bland and soothing effect associated with its oily nature. In the tentative final monograph for OTC anorectal drug products, the agency affirmed that Panel's Category I classification of cod liver oil and specified that the ingredient may not be used as a sole protectant ingredient but may be used in combination with one, two, or three other protectant active ingredients. (See 53 FR 30756 at 30767; August 15, 1988.)

Based on the agency's market survey discussed above, the agency is not aware of any diaper rash drug products that contain cod liver oil as a single protectant ingredient. Accordingly, the agency is proposing that cod liver oil in diaper rash drug products may be used only in combination with certain other skin protectant active ingredients within the concentrations specified in proposed § 347.10.

Cod liver oil is recognized in the current United States Pharmacopeia/National Formulary (Ref. 10). Cod liver oil U.S.P. is assayed in terms of its vitamin A and cholecalciferol (vitamin D) content and contains in each gram not less than 850 U.S.P. units of vitamins A and 85 U.S.P. units of vitamin D. (One U.S.P. unit is equivalent to one International Unit.) The Hemorrhoidal Panel recommended a maximum daily dose of 10,000 U.S.P. units for vitamin A and 400 U.S.P. units for cholecalciferol per 24 hours (45 FR 35576 at 35630). The agency proposed this dosage for this ingredient in the tentative final monograph for OTC anorectal drug products (53 FR 30756 at 30782) and believes that these maximum daily doses would also be appropriate for diaper rash use of these ingredients.

Considering that cod liver oil contains a minimum of 850 units per gram (g) of vitamin A and 85 units per g of vitamin D, the product with 13.56 percent cod liver oil containing these minimum levels would reach the maximum daily dose with 35 g of product. This quantity exceeds the amounts likely to be used by the average consumer. The Hemmorhoidal Panel assumed an average dose of 2 g for protectants (45 FR 35627). Even if a diaper rash product were applied 10 or more times a day, the maximum daily dose (10,000 U.S.P. units for vitamin A and 400 U.S.P. units for cholecalciferol) being proposed by the agency for this ingredient in this tentative final monograph would not be exceeded. Manufacturers that use cod liver oil containing more than the minimum levels will have the responsibility to formulate and label their product so that this maximum daily dose will not be exceeded.

Based on the Hemorrhoidal Panel's evaluation and the other information stated above, the agency is proposing to classify cod liver oil (5 to 13.56 percent) as Category I for use in OTC diaper rash drug products in this tentative final monograph as follows:

Cod liver oil, in accordance with § 347.20(e), provided that the product is labeled so that the amount of the product that is used in a 24-hour period represents a quantity that provides 10,000 U.S.P. units of vitamin A and 400 U.S.P. units of cholecalciferol.

The agency invites comments and supporting data on the appropriateness of this and other amounts of cod liver oil as an active ingredient in drug products labeled for the prevention and treatment of diaper rash and on this proposal to limit use of this ingredient to

combination skin protectant diaper rash drug products.

Cod liver oil for skin protectant uses other than for diaper rash will be addressed in the final monograph for OTC skin protectant drug products in a future issue of the Federal Register.

References

(1) Comment No. C00030, Docket No. 78N–0021, Dockets Management Branch.
(2) OTC Volume 160021.
(3) Comment No. C00058, Docket No. 78N–0021, Dockets Management Branch.
(4) OTC Volume 160245.
(5) Grayzel, H.G., C. B. Heimer, and R. W. Grayzel, "The Value of Cod Liver Oil Ointment and Cod Liver Oil Lotion in the Treatment of Dermatoses," New York State Journal of Medicine, 53:2233–2237, 1953.
(6) Lee, J.R., "Clinical Facts of Desitin Ointment," reprinted from "International Review of Medicine and Surgery," London, 1939.
(7) Verbov, J., "Common Eruptions in the Napkin Area," The Practitioner, 220:779–784, 1978.
(8) Smith, G.H., "Diaper Rash and Prickly Heat Products," in "Handbook of Nonprescription Drugs," 8th Ed., American Pharmaceutical Association, Washington, pp. 643–653, 1986.
(9) Kastrup, E.K., editor, "Topical Diaper Rash Products," in "Facts and Comparisons," J.B. Lippincott Co., St. Louis, p. 563, August 1987.
(10) "The United States Pharmacopeia XXII—The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 344–345, 1989.

J. Comments on Colloidal Oatmeal

15. One comment, regarding several products containing colloidal oatmeal as the principal active ingredient, was submitted in response to the publication of the tentative final monograph for OTC external analgesic drug products (February 8, 1983; 48 FR 5852). The comment submitted data and requested that FDA include colloidal oatmeal in the monograph for OTC external analgesic drug products as an ingredient generally recognized as safe and effective for the following indications: "For prompt temporary relief of itchy, sore, sensitive skin due to rashes, eczema/psoriasis, hemorrhoidal and genital irritations, diaper rash, chicken pox, prickly heat, hives, poison ivy/oak, and sunburn."

Elsewhere in this issue of the Federal Register, the agency is addressing one aspect of the comment's request: The antipruritic (anti-itch) use of colloidal oatmeal for diaper rash. The agency will address the antipruritic use of colloidal oatmeal for the other conditions described in the comment in a future Federal Register publication pertaining to the rulemaking for OTC external analgesic drug products. The use of colloidal oatmeal as a skin protectant is discussed in comment 16 below.

16. One comment requested that colloidal oatmeal be included in the skin protectant monograph as a safe and effective ingredient for the claim: "For prompt temporary relief of itchy, sore, sensitive skin due to: * * * diaper rash * * *." The comment based its request on the Miscellaneous External Panel's review of colloidal oatmeal as an antipruritic at that Panel's 23rd meeting on January 29 and 30, 1978. The comment noted that the Panel found colloidal oatmeal at all concentrations to be safe and effective as a bath additive, cleansing bar, and soak for the treatment of dry skin and the resultant itching (Ref. 1).

The comment contended that colloidal oatmeal falls within the Topical Analgesic Panel's definition of a skin protectant, because due to its physical and chemical properties it isolates exposed skin or mucous membrane surface from harmful or annoying stimuli (see proposed § 347.3 at 43 FR 34648). Moreover, the comment added, colloidal oatmeal meets the Panel's criteria described at 43 FR 34630 in that it protects by mechanical or other physical means, is inert, insoluble, finely subdivided, and adsorbs some moisture. The comment stated that colloidal oatmeal that is dispersed in water and applied to the skin deposits particles on the skin and leaves behind an occlusive film barrier that is helpful in protecting skin against irritation and in soothing irritated skin conditions. The comment added that colloidal oatmeal when added to water controls the osmotic pressures of water with respect to the skin and permits adequate water to enter into the stratum corneum. The comment stated that the oatmeal leaves behind a thin occlusive film on the skin and this serves to hold in the adsorbed moisture. The result of this coating is that the skin is protected against irritation. The comment concluded that for these reasons colloidal oatmeal should be classified in Category I as a skin protectant for diaper rash.

The comment's anti-itch claim is discussed in the notice of proposed rulemaking to amend the tentative final monograph for OTC external analgesic drug products published elsewhere in this issue of the Federal Register. The agency concluded that colloidal oatmeal could not be used in an OTC diaper rash drug product bearing an anti-itch claim but could be used in OTC diaper rash drug products bearing only skin protectant claims. In this document, the agency is addressing only skin protectant claims for diaper rash drug products.

The agency agrees that colloidal oatmeal qualifies as a skin protectant because of its barrier-like properties. However, after reviewing the data submitted by the comment (Ref. 2), the agency concludes there is insufficient information to demonstrate that colloidal oatmeal is safe and effective when used as a bath, soak, or cleansing bar for the treatment or prevention of diaper rash. Most of the data that were submitted involved relief of itching due to dry skin conditions. Only one report (Ref. 3) described the use of colloidal emollient baths (colloidal oatmeal impregnated with 35 percent liquid oils) as adjuvant therapy in various pediatric dermatoses including 30 patients with intertrigo and diaper rashes. The article stated that in this bathing procedure some of the bath water is imbibed by the skin tissues, thereby softening the skin. The water is retained in the skin by means of a thin occlusive film of oil which remains on the skin and acts as an effective barrier by retarding the evaporation of water from the skin surface, keeping the stratum corneum hydrated.

In order to evaluate the effectiveness of these colloidal emollient baths, a study was conducted on 152 pediatric patients with various dermatoses associated with dryness of the skin. Thirty of these patients had contact dermatitis, which included intertrigo and diaper rashes. When indicated, other specific medicaments such as corticosteroid and antibiotic preparations were used. It is not clear from the report whether any of these other medicaments were used on the patients with diaper rash. The author reported that the baths of colloidal oatmeal in a super oil form proved to be an excellent adjunct to the therapy used. It was also noted that the baths were used as a routine cleansing and protective measure even after the dermatoses had completely subsided.

For several reasons, the agency does not consider these data adequate to support the use of colloidal oatmeal for the prevention or treatment of diaper rash. First, it is unclear whether the desirable product to use would be colloidal oatmeal or colloidal oatmeal impregnated with 35 percent liquid oils. The comment reports that colloidal oatmeal contains 46 percent carbohydrate, 9 percent oil, 24 percent protein, 8 percent moisture, and a negligible amount of crude fiber. There is no evidence from the data submitted that the product with 9 percent oil will leave a sufficient protective film of oil on the skin. The only data submitted on use of the ingredient on patients with

diaper rash involved the use of the oilated colloidal oatmeal (impregnated with 35 percent liquid oils). It is unclear what these liquid oils are, and what the total "oil" content of this product is.

The agency also has some additional concerns about the use of this ingredient for diaper rash conditions. It is unclear how hydrating the skin in the diaper area (which skin may already be well hydrated from urine) and occluding the skin can aid in treating or preventing diaper rash. The Miscellaneous External Panel, in its discussion of diaper rash, implicated wetness and occlusion in contributing to or worsening diaper rash (47 FR 39436 at 39440). Also, in this tentative final monograph, the agency is proposing the claims "helps protect from wetness" and "helps seal out wetness" for skin protectant drug products used for diaper rash. As discussed in the report (Ref. 3) submitted by the comment, it appears that the colloidal oatmeal could seal in wetness. Accordingly, because of the lack of data demonstrating safety and effectiveness for use for diaper rash, the agency is classifying colloidal oatmeal in Category III for diaper rash. The use of colloidal oatmeal for other skin protectant claims will be addressed in another document related to the rulemaking for OTC skin protectant drug products, to be published in a future issue of the Federal Register.

As noted above, the comment described colloidal oatmeal as containing 46 percent carbohydrate, 9 percent oil, 24 percent protein, 8 percent moisture, and negligible amount of crude fiber. In the tentative final monograph for OTC skin protectant drug products for poison ivy, poison oak, poison sumac, and insect bites (54 FR 40808 at 40810), the agency stated that it does not find this information to be an adequate public standard for colloidal oatmeal. There are no publicly available chemical standards that can be used by any manufacturer who wishes to utilize colloidal oatmeal as an ingredient in its product(s). In order for colloidal oatmeal to be generally recognized as safe and effective as a skin protectant, the agency must have sufficient data on the composition and concentration of the different constituents and the quantity (range) of each that is contained in marketed products. For an ingredient or mixture to be included in an OTC drug final monograph, it is necessary to have publicly available chemical information that can be used by all manufacturers to determine that the ingredient is appropriate for use in their products. In the tentative final monograph for OTC skin protectant drug products for poison ivy, poison oak, poison sumac, and insect bites (54 FR 40810), the agency stated that it would be appropriate for interested parties to develop with the United States Pharmacopeial Convention appropriate standards for the quality and purity of colloidal oatmeal. Should interested parties fail to provide necessary information so that an appropriate standard may be established, colloidal oatmeal will not be included in a final monograph.

References

(1) Summary Minutes of the Twenty-Third Meeting of the Advisory Review Panel on OTC Miscellaneous External Drug Products, January 29 and 30, 1978, Dockets Management Branch.

(2) OTC Volumes 160069 and 160070.

(3) Dick, L. A., "Colloidal Emollient Baths in Pediatric Dermatoses," Archives of Pediatrics, 75:506–508, 1958.

K. Comments on Corn Starch

17. In response to the tentative final monograph for OTC skin protectant drug products published in the Federal Register of February 15, 1983 (48 FR 6820), one comment disagreed with the agency's 97 percent limitation of the concentration of corn starch "to allow for formulation with a dessicant or other pharmaceutical necessity." The comment contended that the agency's prescribing the method of formulation of active ingredients is inappropriate where evidence of safety or efficacy concerns is nonexistent. The comment noted that formulations containing corn starch at levels approaching 100 percent have been successfully marketed. The comment recommended that the agency drop all formulation-related constraints on concentration levels when corn starch is reviewed for use in diaper rash drug products and extend the concentration range to provide for products containing 10 to 100 percent. However, the comment did acknowledge that formulations containing 100 percent corn starch do not now exist.

The Topical Analgesic Panel recommended a concentration range of 10 to 85 percent for the topical application of corn starch (43 FR 34628 at 34636). The Panel noted, however, that because corn starch is so absorptive of water, a sticky mass may form when it is used alone (i.e., at 100 percent). Therefore, another finely dispersed dessicant is usually incorporated in a formulation for use as an absorbent.

In response to comments received on the Panel's recommendation, the agency tentatively agreed in the tentative final monograph for OTC skin protectant drug products that an increase to 97 percent rather than 100 percent would be appropriate to allow for formulation with a dessicant or other pharmaceutical necessity (48 FR 6820 at 6826). The agency did not include corn starch in the tentative final monograph because its primary OTC drug use seemed to be in diaper rash drug products. The agency also deferred its proposal on the appropriate upper concentration limit for corn starch until its use in diaper rash drug products was reviewed.

Corn starch is listed among the ingredients marketed for diaper rash in the Miscellaneous External Panel's statement on OTC drug products for the treatment of diaper rash (47 FR 39436 at 39439). The agency reviewed the submissions on diaper rash drug products that contain corn starch as an active ingredient and found the following concentrations in different dosage forms: 9.52 percent in an ointment (Ref. 1), 41 percent in a powder (Ref. 2), and 96 percent in another powder (Ref. 3). Another powder product (labeled for the prevention and treatment of diaper rash, among other claims) was submitted to the Topical Analgesic Panel (Ref. 4). The submission states that this product contains 71.4 percent corn starch. The agency has been informed that the product currently contains 83.2 percent corn starch (Ref. 5). The agency also notes that in the tentative final monograph for OTC skin protectant drug products the change to a higher concentration was in response to a comment whose own product contained 96 to 97 percent corn starch. The current labeling for this same product shows that it now contains 98 percent corn starch (Ref. 6).

The agency continues to believe that without a dessicant or other pharmaceutical necessity, corn starch (at a 100 percent concentration) is likely to form a sticky mass when it absorbs moisture. The comment did not provide any data showing that 100 percent corn starch would not form a sticky mass when it absorbs moisture. As the comment pointed out, formulations containing 100 percent corn starch do not now exist. If appropriate data are submitted, the agency will then consider raising the allowable concentration to 100 percent. In the interim, based on the 98 percent product that has apparently been marketed without any problems, the agency proposes to increase the upper concentration limit for corn starch from 97 percent to 98 percent. This revised upper concentration would still allow for formulation of products with a dessicant or other pharmaceutical necessity to prevent a sticky mass from

forming. Accordingly, based on the above, the agency is proposing that corn starch at a concentration of 10 to 98 percent be classified in Category I for the treatment and prevention of diaper rash.

Although "corn starch" has been used as the name for the starch used in diaper rash products, "topical starch" is the official title used in the United States Pharmacopeia XXII (Ref. 7). Therefore, "topical starch" is the name proposed for this ingredient in this tentative final monograph.

References

(1) OTC Volume 160040.
(2) OTC Volumes 160077 and 160091.
(3) OTC Volumes 160242 and 160427.
(4) OTC Volume 060137.
(5) Memorandum of telephone conversation between D. Whittington, Plough Inc., and L. Geismar, FDA, dated July 8, 1987, in OTC Volume 06DRSTFM, Docket No. 78N–021D, Dockets Management Branch.
(6) Current labeling for Johnson & Johnson Baby Powder, in OTC Volume 06DRSTFM, Docket No. 78N–021D, Dockets Management Branch.
(7) "The United States Pharmacopeia, XXII—The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD., p. 1276, 1989.

18. Two submissions to the Miscellaneous External Panel (Ref. 1) contained data on the safety and effectiveness of a product containing corn starch as an active ingredient for the prevention and treatment of diaper rash. Other submissions (Refs. 2 and 3) contained studies on corn starch and Candida albicans (*C. albicans*). Two other submissions (Refs. 4 and 5) were for products in which corn starch was an inactive ingredient.

In the advance notice of proposed rulemaking for OTC skin protectant drug products (August 4, 1978; 43 FR 34628), the Topical Analgesic Panel recommended corn starch as safe and effective for OTC use as a skin protectant based on its absorbent properties. The Panel indicated that there are no reported incidents of adverse effects to the topical application of corn starch and that its absorptive properties surpass any powder described in the official compendia. The Panel classified corn starch in Category I at a concentration range from 10 to 85 percent (43 FR 34635 to 34636).

The agency did not include corn starch in the tentative final monograph for OTC skin protectant drug products (February 15, 1983; 48 FR 6820), but deferred classifying it until its use in diaper rash drug products (the primary OTC use) was reviewed (48 FR 6828). However, in response to a comment, the agency tentatively raised the concentration limit to 97 percent. (See 48 FR 6826 comment 15.)

In the Miscellaneous External Panel's statement on OTC diaper rash drug products, the use of corn starch for diaper rash was referred to the rulemaking for OTC skin protectant drug products because these products provide mechanical or physical protection and may prevent further skin irritation associated with diaper rash (September 7, 1982; 47 FR 39436 at 39439). Although the Panel did not discuss corn starch in its statement, it did discuss this ingredient at its 30th meeting, on March 12, 1979 (Ref. 6), and expressed concern about corn starch promoting the growth of *C. albicans* when used on the skin of the diaper area and thus contributing toward skin infections. Others (Refs. 7, 8, and 9) also report that corn starch serves as a culture medium for microorganisms, especially *C. albicans*, an organism that is part of the normal colonic flora. However, Honig (Ref. 9) reports that an unpublished study by Leyden indicates that corn starch applied to human skin does not serve as a culture medium for *C. albicans* and does not promote or aggravate dermatitis due to *C. albicans*.

The unpublished studies by Leyden (Refs. 2 and 3) were submitted to the Panel to support the safety of 100 percent corn starch for use as a diaper rash powder. In one study (Ref. 2), three sites on each forearm of six subjects were inoculated with *C. albicans*. After the inoculum dried, the sites on one forearm were covered with plastic film and the edges sealed with tape. The sites on the other forearm were covered with 150 milligrams (mg) of corn starch (used for cooking purposes), covered with plastic film, and sealed with tape. Quantitative cultures and clinical assessments were obtained 24 hours after the sites were prepared. The sites treated with corn starch did not show increased numbers of *C. albicans*, which could occur if the organism was using corn starch as a nutrient. There was a definite trend for less *C. albicans* and aerobic organisms on the sites treated with corn starch. This reduced growth may have been due to a drying effect of the corn starch because of its absorption of water. In a second similar study (Ref. 3) with nine subjects, 100 percent corn starch U.S.P. was compared with a product containing 96.29 percent corn starch U.S.P., 3.50 percent magnesium carbonate N.F., 0.059 percent methylbenzethonium chloride, and 0.15 percent perfume, and was also compared with untreated controls. The conclusion from the two studies that were conducted under exaggerated conditions was that corn starch did not act as a nutrient for *C. albicans* on human skin and would not promote or aggravate dermatitis caused by this organism.

The animal and human safety studies included in two of the submissions (Ref. 1) were for the total formulation of a product in which corn starch, at a concentration of 41 percent, was one of the active ingredients. The studies were not designed specifically to show the safety of corn starch as a single active ingredient or at a 100 percent concentration.

In another submission (Ref. 4), the manufacturer stated that, based on references it cited (Refs. 10 through 13), there are no known toxic effects when corn starch was administered externally. Corn starch was present in the ointment product at a concentration of 9.52 percent. Although listed as an active ingredient in the submission, the product's label did not claim that it is active. In fact, the efficacy data in the submission stated that the starch provides a stiffer consistency (to aid stability when the product is subjected to changes in atmospheric temperatures) and smoothness to the ointment. The agency finds these to be characteristics of a pharmaceutical necessity, and not an active ingredient. The agency has reviewed the references cited in the submission and determined that they do not contain any statements about there being no known toxic effects when corn starch is applied externally, and especially no statements about use in diaper rash.

The agency concludes that if the proposed directions for diaper rash drug products are followed (see comment 7 above), (that is, to change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry), this will help reduce the number of microorganisms in the diaper area, including *C. albicans*. Gossel (Ref. 8) states that moisture enhances microbial growth and increases the chance of rash. The Topical Analgesic Panel noted that corn starch allows for enhanced evaporation of moisture from the skin by increasing the surface area available, and microorganisms are absorbed and suspended by the corn starch (43 FR 34628 at 34636). The evaporation of moisture and the absorption of microorganisms help reduce the growth of microorganisms in the diaper area because many microorganisms require moisture to survive. Accordingly, the agency tentatively concludes that corn starch is safe for use in diaper rash drug products.

Regarding the effectiveness of corn starch, one submission indicated that it

was official in the U.S.P. as a dusting powder, that it prevents friction, is absorptive (drying the skin by taking up water and toxic materials), and it has a cooling effect (provides extra surface area for loss of heat). Like the safety data, the effectiveness studies in these submissions (Ref. 1) apply to the total product in which corn starch was just one of the ingredients. Most of the studies were designed to show the effectiveness of the antimicrobial ingredient in the product.

Based on the Topical Analgesic Panel's Category I classification of corn starch as a safe and effective skin protectant, the Miscellaneous External Panel's recommendation of skin protectants such as corn starch for diaper rash, the additional data reviewed, and the lack of known adverse reactions resulting from its topical use, the agency is classifying corn starch in Category I for the prevention and treatment of diaper rash. As discussed in comment 17 above, the Category I concentration range is from 10 to 98 percent.

References

(1) OTC Volumes 160077 and 160091.
(2) OTC Volume 160362.
(3) OTC Volume 160427.
(4) OTC Volume 160040.
(5) OTC Volume 160242.
(6) Transcript of Proceedings of the Advisory Review Panel on OTC Miscellaneous External Drug Products, March 12, 1979, pp. 225 and 236–237, in OTC Volume 06DRSTFM, Docket No. 78N–021D, Dockets Management Branch.
(7) Arndt, K., "Diaper Rash," In "Manual of Dermatologic Therapeutics—with Essentials of Diagnosis," 2d Ed., Little, Brown and Co., Boston, 1978.
(8) Gossel, T.A., "Diaper Dermatitis," U. S. Pharmacist, September: 34–40, 1984.
(9) Honig, P.J., "Diaper Dermatitis," Postgraduate Medicine, 74:79–88, 1983.
(10) "The United States Pharmacopeia," 18th Revision, United States Pharmacopeial Convention, Inc., Rockville, MD, 1970.
(11) "The National Formulary," 13th Ed., American Pharmaceutical Association, Washington, 1940.
(12) Osol, A., R. Pratt, and M.D. Altschule, editors, "The United States Dispensatory," 26th Ed., J.B. Lippincott Co., Philadelphia, 1967.
(13) Krantz, J.C., and C.J. Carr, "Pharmacological Principles of Medical Practice," 5th Ed., Williams and Wilkins, Baltimore, 1961.

L. Comments on Dexpanthenol.

19. Two drug manufacturers made submissions to the Miscellaneous External Panel (Refs. 1, 2, and 3) on their products containing dexpanthenol and requested Category I classification for the products.

The submissions were reviewed by the Panel in preparing its statement on diaper rash drug products, but the Panel did not classify any of the ingredients in these products. (See 47 FR 39436.) One manufacturer's product was a cream containing vitamin A palmitate, vitamin D_2, dexpanthenol (5 percent), and vitamin E (as dL-alpha-tocopheryl acetate) and was labeled for "temporary relief of irritation, pain, and itching in * * * diaper rash * * *," (Ref. 1). The manufacturer of this product subsequently advised FDA that its product had been repositioned as a cosmetic and requested that its submission (Ref. 1) be deleted from consideration as an OTC drug product (Ref. 4). Accordingly, the submission is no longer being considered in this rulemaking.

The second manufacturer's products (marketed as a cream or lotion) contained dexpanthenol (2 percent), menthol, and camphor and were labeled "for relief of itching and discomfort in minor skin disorders * * *. Useful in diaper rash * * *," (Ref. 2). The manufacturer has advised FDA that its lotion product is no longer marketed, and provided a copy of the current labeling for the cream product (dexpanthenol 2 percent), which states that it "relieves skin itching and irritation; aids healing; for use in * * * diaper rash * * *," (Ref. 5).

The agency has reviewed the submissions for this product, which included an unpublished study on animal safety and published reports of clinical experience in using dexpanthenol for various dermatoses (Refs. 2 and 3). In a 14-day animal safety study (Ref. 6), three preparations containing 2 percent dexpanthenol were orally administered to groups of six rats at a dose level of 50 milliliters/kilogram (mL/kg); no toxic effects were noted during observations for body weight and mortality. No information was provided about the treatment of the control group. Three of the reports of clinical experience (Refs. 7 through 10) included data on the use of dexpanthenol for the treatment of diaper rash. Kline (Ref. 7) summarized 12 years of clinical experience with a dexpanthenol cream and included an analysis of 500 case reports of dermatologic patients (28 were cases of diaper rash) to show that a wide variety of skin conditions were amenable to therapy with generally satisfactory results. Of the 28 cases of diaper dermatitis, satisfactory results were reported in 23 cases and unsatisfactory results in 5 cases. However, no other information is provided. Referring to a study by Litchfield (Ref. 8), Kline noted that Litchfield did not find any sensitization or rebound when 66 infants and children with various pediatric skin problems, including diaper rash, were treated with a combination product containing dexpanthenol and hydrocortisone. Kline and Caldwell (Ref. 9) treated 31 patients with various types of skin conditions, including 1 case of diaper rash, with either a 2 percent or 5 percent dexpanthenol cream and concluded that a concentration of 2 percent was just as effective as a concentration of 5 percent. No evidence of sensitization or other adverse effects were observed in these patients, some of whom were treated for over 1 year. Dubow (Ref. 10) described the treatment of diaper rash using dexpanthenol cream for relief of inflammation, in conjunction with other treatments, i.e., drying the diaper area and eliminating ammonia in contact with the skin. None of these authors provided detailed information on the procedures used, controls, or severity of the infants' diaper rash. These reports provide some limited evidence of the safety and effectiveness of dexpanthenol, but the data are inadequate to establish general recognition of the safety or effectiveness of dexpanthenol in the treatment of diaper rash.

Accordingly, the agency concludes that there are insufficient data available to classify dexpanthenol as safe or effective for the treatment or prevention of diaper rash and classifies the ingredient as Category III.

References

(1) OTC Volume 160067.
(2) OTC Volume 160104.
(3) OTC Volume 160204.
(4) Letter from S. Most, Block Drug Company, Inc., to L. Geismar, FDA, November 6, 1986, in OTC Volume 06DRSTFM, Docket No. 78N–021D, Dockets Management Branch.
(5) Letter from A. Ryan, Armour Pharmaceutical Co., to L. Geismar, FDA, January 7, 1987, in OTC Volume 06DRSTFM, Docket No. 78N–021D, Dockets Management Branch.
(6) "Acute Toxicity of Panthoderm®Cream, pantho-F® 1% and Panthoderm®Lotion," Project 0115, 1974, unpublished study, in OTC Volume 160104.
(7) Kline, P. R., "12 Years' Experience Using Pantothenylol Topically," Western Medicine, 4:78–80 and 100, 1963.
(8) Litchfield, H. R., "Treatment of Intertriginous Eruptions (Diaper Rash) and Infantile Eczemas," New York State Journal of Medicine, 60:3252–3257, 1960.
(9) Kline, P. R., and A. Caldwell, "Treatment of Various Dermatoses with Topical Application of Panthenol," New York State Journal of Medicine, 52:1141–1143, 1952.
(10) Dubow, E., "Ammoniacal Napkin Dermatitis in Infants," Archives of Pediatrics, 71:323–326, 1954.

M. Comments on Dimethicone

20. Two comments noted that silicone was identified on the agency's list of 50 ingredients in the advance notice of proposed rulemaking for OTC diaper rash drug products (47 FR 39439) but that it was not referred to any specific rulemaking. The comments recommended that silicone (dimethicone) be included in the skin protectant rulemaking and be classified as Category I for the treatment and prevention of diaper rash because this ingredient is generally recognized and commonly used for its properties of barrier-like action (especially to irritants which cause common diaper rash), water insolubility, and emollience.

The comments are correct that silicone, which is on the list of ingredients submitted to the Miscellaneous External Panel, was not referred to any of the four specific rulemakings in which OTC diaper rash drug products are being evaluated. Silicone is a general term, but it is often used to describe dimethicone (Refs. 1 and 2). Dimethicone is the preferred nomenclature because it identifies a defined compound that is official in The National Formulary (Ref. 3). Because there are various silicone compounds (Ref. 4), the agency is not classifying silicone per se, but is considering the only silicone ingredient for which data have been submitted, i.e., dimethicone.

The Topical Analgesic Panel recommended that 1 to 30 percent dimethicone, a water-repellent silicone oil (Ref. 4), be placed in Category I as a skin protectant for use on infants, children, and adults (43 FR 34628 at 34637). The agency concurred with the Panel's recommendations on dimethicone in the tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6832). Based on the recommendations of the Topical Analgesic Panel, the agency is classifying dimethicone, 1 to 30 percent, as Category I for the treatment or prevention of diaper rash. (See comment 8 above.)

References

(1) Marler, E.E.J., "Pharmacological and Chemical Synonyms," "Excerpta Medica," 7th Ed., Amsterdam, 1983, s. v. "dimeticone," "dimethicone," "silicone," and "simethicone."

(2) Billups, N.F., "American Drug Index," 32d Ed., J.B. Lippincott Co., Philadelphia, 1988, s. v. "silicone."

(3) "The United States Pharmacopeia XXII—The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, pp. 1927–1928, 1989.

(4) Harvey, S.C., "Topical Drugs," in "Remington's Pharmaceutical Sciences," 17th Ed., edited by A. Gennaro, Mack Publishing Co., Easton, PA, pp. 773–775, 1985.

N. Comments on Lanolin

21. Two comments recommended Category I status for lanolin as a skin protectant for the treatment and prevention of diaper rash, stating that this ingredient is safe and acts as an effective barrier to irritants that cause common diaper rash. A third comment requested that lanolin be categorized as an active ingredient in the skin protectant rulemaking for use as a single ingredient or in combination, as permitted by the monograph, with an indication for the prevention of diaper rash. In support of the safety and effectiveness of lanolin as a skin protectant, the latter comment cited data submitted to the Miscellaneous External Panel (Ref. 1). The comment stated that animal and human test data included in the submission demonstrate lanolin's low order of irritation and sensitization, and that other data show that lanolin meets the definition of a skin protectant (an agent that protects injured or exposed skin or mucous membranes from harmful or annoying stimuli). The comment also based its request for a diaper rash prevention indication on the Topical Analgesic Panel's affirmation of this use for petrolatum (43 FR 34628 at 34639) and the Hemorrhoidal Panel's Category I classification of lanolin and petrolatum as protectants (45 FR 35576 at 35632 and 35634). To confirm the ability of these agents to protect the diaper area, the comment cited the Hemorrhoidal Panel's statement that "the barrier effect is supported by data indicating that infants' perianal skin is afforded significant protection against diaper wetness by application of a continuous film of petrolatum applied to the skin in the diaper area," (45 FR 35627). The comment also referred to an evaluation of moisturizers performed by Kligman, Grove, and Studemayer (Ref. 2) in which petrolatum and lanolin were determined to be the best moisturizers. Finally, the comment contended that the Ophthalmic panel's Category I classification of lanolin for treating conditions involving ocular membranes (an area more sensitive than the epidermis) (45 FR 30002 at 30044) further supports the safe and effective use of lanolin as a skin protectant for diaper rash.

Although lanolin is widely marketed and contained in many diaper rash products (Ref. 3), as well as other topical drug products, it has not been classified in the rulemaking for OTC skin protectant drug products. Lanolin was listed as one of the ingredients in marketed products submitted to the Miscellaneous External Panel in its statement on OTC drug products for the treatment of diaper rash (47 FR 39436 at 39439). In addition, as the comment noted, the Ophthalmic Panel classified lanolin as Category I as an ophthalmic emollient but did not establish a concentration range (45 FR 30002 at 30048). The Hemorrhodial Panel also classified lanolin Category I as a protectant at a concentration of at least 50 percent per dosage unit (45 FR 35576 at 35673). The agency concurred with these classifications in the tentative final and final monographs for OTC ophthalmic drug products (48 FR 29788 at 29798 and 53 FR 7076 at 7089) and in the tentative final monograph for OTC anorectal drug products (53 FR 30756 at 30782). In the final monograph for OTC ophthalmic drug products, the agency specified the concentration range for lanolin and anhydrous lanolin, as an emollient, to be 1 to 10 percent in combination with one or more oleaginous emollients included in the monograph (53 FR 7089).

The agency has reviewed the data submitted on lanolin and agrees that it qualifies as a skin protectant active ingredient for the treatment and prevention of diaper rash. Lanolin has a low sensitization potential and acts as an effective barrier to irritants that cause common diaper rash. Safety data on lanolin included in the submission (Ref. 1) consisted of reports of controlled animal and human studies and pertinent medical and scientific literature. The topical irritation potential of lanolin was determined by two primary irritation studies on rabbits: the Draize procedure demonstrated that lanolin was not a primary irritant, and the other study found lanolin to be slightly irritating at a 20-percent concentration in oil and nonirritating at a 10-percent concentration. There were no toxic symptoms or deaths when a 25-percent solution of lanolin in corn oil was given orally to mice. The acute oral LD^{50} (dose lethal to 50 percent of test animals) by gastric intubation in rats was estimated to be greater than 5 grams per kilogram. A 24-hour patch test on 10 humans with 10 percent lanolin in corn oil proved to be nontoxic and nonirritating.

The major safety consideration relates to the allergenicity of lanolin, and this is discussed by the Hemorrhoidal Panel in its advance notice of proposed rulemaking for OTC anorectal drug products. (See 45 FR 35632; May 27, 1980.) That Panel indicated that the data show that the incidence of lanolin allergy is extremely low. The agency is aware of other reports that further support the low incidence of lanolin

allergy. Weston and Weston (Ref. 4) report that lanolin has been thought to be a cause of contact allergy in children, but only two instances have been recorded in the literature. According to Weston and Weston, children who frequently apply lanolin to their skin for conditions such as atopic dermatitis or psoriasis do not develop an allergy to lanolin despite the long-term exposure. Kligman (Ref. 5) concluded that lanolin is an extremely weak sensitizer and its reputation as an allergen has been vastly inflated. Although lanolin may cause allergic reactions in sensitive individuals, the agency agrees with the Hemorrhoidal Panel (45 FR 35576 at 35632) and tentatively concludes that this ingredient can be used safely by the major part of the OTC target population and that no special warnings are needed. Further, the labeling of lanolin as an ingredient in the product should serve to alert sensitive individuals to its presence in the product.

The effectiveness data provided in the submission (Ref. 1) consist of pertinent medical and scientific literature that substantiates the activity of lanolin as a protectant and emollient. Although the literature does not contain controlled studies specific for diaper rash, it shows that the activity of lanolin is based on emollience, lubrication, and occlusiveness. These physical properties along with the findings of the Hemorrhoidal and Ophthalmic Panels are considered sufficient to support effectiveness for preventing and treating diaper rash. Although considered a safe and effective skin protectant for use in diaper rash drug products, none of the data include the concentration used for lanolin as an active ingredient in the various diaper rash products.

The agency has surveyed the marketplace (Refs. 3, 6, and 7) and found that lanolin is widely used as an ingredient in OTC diaper rash products. Products containing lanolin are currently being marketed with diaper rash claims such as "helps protect against urine and other irritants," and "provides a physical barrier" (Ref. 6). The Handbook of Nonprescription Drugs (Ref. 3) identifies 15 products that contain lanolin. Lanolin is often described as a base or vehicle (Refs. 3 and 6). It appears that lanolin is being marketed in diaper rash drug products only in combination with other ingredients, such as petrolatum and zinc oxide. Further, in the various submissions and in the Handbook of Nonprescription Drugs (Ref. 3), the concentration of lanolin (15.5 percent) is listed for only one product. Based on the primary irritation studies conducted on rabbits (Ref. 1), which showed lanolin to be slightly irritating at a 20-percent concentration and nonirritating at a 10-percent concentration, the agency does not believe that lanolin in diaper rash drug products should exceed 15.5 percent. Therefore, in this tentative final monograph, the agency is proposing a concentration of 15.5 percent lanolin, based on the only information available. The agency will consider revising this concentration if other supportive data are submitted.

Further, based on the agency's market survey, which showed that lanolin is used only in combination with other diaper rash ingredients, and the agency's actions in the rulemakings for OTC anorectal and ophthalmic drug products (see above), the agency is proposing that lanolin in diaper rash drug products may be used only in combination with certain other skin protectant active ingredients within the concentrations specified in proposed § 347.10. The agency invites comments and supporting data on the appropriateness of this and other concentrations of lanolin as an active ingredient in drug products labeled for the prevention and treatment of diaper rash and on this proposal to limit use of this ingredient to combination skin protectant diaper rash drug products.

References

(1) OTC Volume 160179.
(2) Kligman, A.M., G.L. Grove, and T.J. Studemayer, "Some Aspects of Dry Skin and its Treatment," in "Safety and Efficacy of Topical Drugs and Cosmetics," edited by A.M. Kligman and J.J. Leyden, Grune & Stratton, New York, p. 235, 1982.
(3) Smith, G.H., "Diaper Rash and Prickly Heat Products," in "Handbook of Nonprescription Drugs," 8th Ed., American Pharmaceutical Association, Washington, pp. 651–653, 1986.
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(5) Kligman, A.M., "Lanolin Allergy: Crisis or Comedy," Contact Dermatitis, 9:99–107, 1983.
(6) Huff, B. B., editor, "Physicians' Desk Reference For Nonprescription Drugs," 10th Ed., Medical Economics Co., Inc., Oradell, NJ, pp. 552, 573, and 682, 1989.
(7) Kastrup, E. K., editor, "Topical Diaper Rash Products," in "Facts and Comparisons," J. B. Lippincott Co., St. Louis, p. 563, August 1987.

O. Comment on Live Yeast Cell Derivative

22. In response to the advance notice of proposed rulemaking for OTC skin protectant drug products (43 FR 34628), the agency received a comment requesting removal of the Topical Analgesic Panel's limitation against the use of shark liver oil and live yeast cell derivative on children under 2 years of age without consulting a physician (Ref. 1). The comment argued that the Panel gave no reason for limiting the use of these ingredients and stated that both ingredients are safe and effective as skin protectants for the treatment of diaper rash for that age group. The comment also stated that the Panel failed to mention that a product containing both shark liver oil and live yeast cell derivative was submitted specifically for diaper rash (Ref. 2).

In its response in the tentative final monograph for OTC skin protectant drug products (see 48 FR 6820 at 6825, comment 12), the agency noted that the product referred to by the comment was listed at 43 FR 34629 as one of the marketed products submitted to the Topical Analgesic Panel. However, that Panel discussed the use of shark liver oil and live yeast cell derivative for use as skin protectants only. The agency deferred a decision on limiting the use of shark liver oil and live yeast cell derivative for use as skin protectants and for the treatment of diaper rash on children under 2 years of age pending completion of the agency's evaluation of diaper rash drug products.

The agency has reviewed the data contained in the submission (Ref. 2) and other available data and concludes that the data are insufficient to support the safe and effective use of live yeast cell derivative for the treatment of diaper rash on children under 2 years of age.

The submission included data to support the safe and effective use of live yeast cell derivative as a wound healing agent based on the ingredient's ability to increase oxygen utilization of dermal tissue, increase collagen formation of tissue, and increase the rate of healing of controlled wounds. The manufacturer stated that diaper rash is a tissue injury (wound) caused chemically (by urine, sweat, or humidity), mechanically (by friction or abrasion), or by inflammation and, consequently, a preparation used for the repair of such tissue injury should primarily possess wound healing properties. The agency's evaluation of the data related to use as a wound healing agent appears in the **Federal Register** of February 15, 1983 (48 FR 6820 at 6823). The agency concluded that there was insufficient evidence of the effectiveness of live yeast cell derivative as a wound healing aid. The majority of the clinical data submitted have concerned wounds, which represent a break in the continuity of the skin in which the wound healing properties of live yeast cell derivative mentioned by

the submission would be beneficial. However, the agency believes that diaper rash amenable to treatment with an OTC drug product does not represent a break in the continuity of the skin comparable to the wounds studied, and the data do not establish that the stated wound healing properties of live yeast cell derivative are significant factors in the healing of diaper rash. The agency's discussion in the Federal Register of February 15, 1983 did not involve the use of live yeast cell derivative in infants. However, the agency notes that the Topical Analgesic Panel, while finding live yeast cell derivative safe, limited its use to adults and children 2 years of age and older. The Panel stated that there is no recommended dosage for children under 2 years of age except under the advice and supervision of a physician (43 FR 34628 at 34646).

The submission (Ref. 2) also contains a brief summary of a diaper rash study conducted by Minsky. The study compared an ointment containing 2,000 units of live yeast cell derivative and 3 percent shark liver oil to an undescribed placebo on 54 newborns with peri-rectal diaper rash. All cases had erythema plus either vesiculation, papulation, or excoriation. The infants were divided into a test group of 29 infants treated with the live yeast cell derivative/shark liver oil combination and a control group of 25 infants treated with the placebo. In the test group 86 percent of the infants were cured or improved as opposed to 76 percent in the control group. No adverse reactions to either treatment were noted. It was noted that the test ointment was of a thick consistency that adhered to the affected area. Although the study demonstrates some benefit of the test ointment over the placebo because of the nature of the test ointment and the fact that it contained both shark liver oil and live yeast cell derivative, no conclusions can be made as to the effectiveness of live yeast cell derivative as a single ingredient. The lack of any adverse reactions in the 29 infants in the test group is not considered sufficient data to generally recognize this ingredient as being safe for the treatment of diaper rash in children under 2 years of age. Therefore, the agency places live yeast cell derivative in Category III for safety and effectiveness for its use in the treatment of diaper rash.

The agency's evaluation of shark liver oil appears in comment 8 above.

References

(1) Comment No. C00006, Docket No. 78N-0021, Dockets Management Branch.
(2) OTC Volume 060113.

P. Comment on Microporous Cellulose

23. A submission to the Miscellaneous External Panel contained data on a product containing 45 percent microporous cellulose labeled to help prevent diaper rash (Ref. 1). The submission included patents for the individual components of microporous cellulose, i.e., microporous alpha cellulose and corn cob derivative. The manufacturer attributed the extraordinary ability of the product to absorb moisture to the microporous alpha cellulose and corn cob derivative content. Although the submission was reviewed by the Panel in preparing its statement on diaper rash drug products, the Panel made no recommendations concerning the individual ingredients.

The agency has reviewed the submission and concludes that the data are insufficient to support the safety and effectiveness of microporous cellulose used for the prevention of diaper rash. The patents included in the submission Provided information on the physical and chemical nature of the components of microporous cellulose, but did not provide any data on the use of this ingredient for diaper rash.

The submission described a patch test conducted on 100 white females using the product. A one-half inch square of clean white blotting paper was impregnated with the product and applied to a previously cleaned site on the subjects' backs and allowed to remain in place for 48 hours. Observations of the site were made immediately after removal of the patch, again after 15 minutes, and again after 24 hours. There was no evidence of any irritation, and the investigator concluded that the product is not a primary irritant. While the agency believes that the patch test is illustrative of the low dermal irritancy of the product, the test did not address the safety of using microporous cellulose on infants' skin under the conditions such as those present in the diaper area, e.g., moisture and friction between opposing skin surfaces. In addition, the ages of the subjects were not provided; therefore, no conclusions on the effect of the product on infant skin can be made.

An in vitro study comparing the absorptive capacities of various marketed powder products was also included in the submission. This study showed a superior moisture absorbing capacity for the submitted product. However, the agency does not consider this study as presenting sufficient effectiveness data to support the use of microporous cellulose to help prevent diaper rash.

Based on the above, the agency is classifying microporous cellulose in Category III for safety and effectiveness for the prevention of diaper rash.

Reference

(1) OTC Volume 160357.

Q. Comments on Mineral Oil.

24. Two comments requested Category I status for mineral oil as a skin protectant for the treatment and prevention of diaper rash. Both comments contended that mineral oil has recognized properties of barrier-like action, water insolubility, and emollience plus a long record of safe and effective use, particularly on infants' skin.

Submissions (Refs. 1, 2, and 3) to the rulemaking for OTC skin protectant drug products included safety data for mineral oil and efficacy data for its use as a skin emollient/lubricant. Diaper rash was included among the labeled uses. The safety data included acute oral toxicity in mice, acute dermal toxicity in rabbits, dermal irritation in rabbits, and occular irritation in rabbits. The LD_{50} was shown to be greater than 20 mL/kg. Mineral oil was not shown to be a primary irritant on the skin, and it caused virtually no eye irritation. The efficacy data for mineral oil consisted of information to show its properties of occlusion, emollience, protection, lubrication, and as a moisturizer. However, none of the data included use on patients with diaper rash.

Mineral oil has been evaluated in two OTC drug rulemakings. In the Federal Register of May 27, 1980, the Hemorrhoidal Panel classified mineral oil in Category I as a protectant for anorectal use in concentrations of at least 50 percent (45 FR 35576 at 35633). In its report, the Panel stated that

> * * * mineral oil is effective as a U protectant. A layer of mineral oil is less effective than petrolatum in reducing moisture loss from the outer layer of the skin of the forearm, but it is significantly greater than other materials tested * * *. This property is also interpreted by the Panel to provide occlusion of the area from external exposure to air, liquids, or other substances within reasonable limits.

The Ophthalmic Panel classified mineral oil in Category I as an ophthalmic emollient (45 FR 30002; May 6, 1980). The agency agreed with this classification in the tentative final (48 FR 29788; June 28, 1983) and final (53 FR 7076; March 4, 1988) monographs for OTC ophthalmic drug products.

Upon surveying the marketplace (Refs. 4 and 5), the agency notes that mineral oil is used as an ingredient in

OTC diaper rash products. In some products, mineral oil is not labeled as an active ingredient and in other products, such as baby oils containing a diaper rash claim, it appears to be an active ingredient, at up to a 100 percent concentration.

The Hemorrhoidal Panel commented that mineral hydrocarbons are not subject to metabolism and can thus remain on the skin indefinitely unless physically removed. The Panel noted that these mineral fats remain on the skin and can produce chronic irritation fibrosis and folliculitis (45 FR 35576 at 35633). The Panel noted a potential problem with repeated application of mineral oil hydrocarbons to fissured anal areas or to raw mucosa, but recommended that mineral oil was safe for use in anorectal products. The Panel further recommended that mineral oil be used in a concentration of at least 50 percent per dosage unit and that use not exceed six applications per 24 hours or after each bowel movement. The agency proposed this usage in the tentative final monograph for OTC anorectal drug products (53 FR 30756 at 30782 and 30784).

The Panel made the following statement about mineral oil at 45 FR 35633:

> Because it is not absorbed, its effect may be prolonged for hours until it is physically removed. The effectiveness of mineral oil and analogous petroleum-derived agents such as lubricants, protective agents, and stable vehicles must be weighed against potential accumulation and persistence until physically removed.

The agency is proposing directions for all diaper rash drug products that include "cleanse the diaper area, and allow to dry." The agency believes that any potential accumulation will be minimized if these directions are followed, and thus there is no need to limit the number of daily applications of a diaper rash drug product containing mineral oil.

The effectiveness data provided in the submission (Ref. 3) consist of pertinent medical and scientific literature that substantiates the activity of mineral oil as a protectant and emollient. Although the literature does not contain controlled studies specific for diaper rash, it shows that the activity of mineral oil is based on emollience, lubrication, and occlusion. These physical properties along with the findings of the Hemorrhoidal and Ophthalmic Panels are considered sufficient to support effectiveness for including mineral oil in the monograph for the prevention and treatment of diaper rash. The agency believes that mineral oil can be safely and effectively used as a single ingredient at up to a 100 percent concentration. The lower concentration is being proposed as 50 percent in accord with the anorectal tentative final monograph. Mineral oil may be combined with other skin protectant active ingredients listed in § 347.10 provided each ingredient in the combination is within the concentrations specified in § 347.10.

References

(1) OTC Volume 160052.
(2) OTC Volume 160086.
(3) Comment No. C00018, Docket No. 78N–0021, Dockets Management Branch.
(4) Sadik, F., "Diaper Rash and Prickly Heat," in "Handbook of Non-Prescription Drugs," 1973 Ed., by G.B. Griffenhagen and L.L. Hawkins, American Pharmaceutical Assocation, Washington, pp. 184–189, 1973.
(5) Kastrup, E.K., editor, "Topical Diaper Rash Products," in "Facts and Comparisons," J.B. Lippincott Co., St. Louis, p. 563, August 1987.

R. Comment on Peru Balsam Oil

25. One manufacturer submitted data (Refs. 1, 2, and 3) to the Miscellaneous External Panel for a combination product that included Peru balsam oil at a concentration of 1.5 percent as an active ingredient, with several labeling claims, one of which was the treatment and prevention of diaper rash. The submissions included tests performed on human newborn infants (Ref. 1), toxicity data, and monographs on Peru balsam oil published by the Research Institute for Fragrance Materials (Ref. 3). Subsequently, the manufacturer informed the agency that the Peru balsam oil in its diaper rash drug products is used as a fragrance at the following concentrations: ointment, 1.5 percent; powder, 0.125 percent; and lotion, 0.32 percent (Refs. 4 and 5).

Balsam Peru and balsam Peru oil were included in the list of ingredients in marketed diaper rash drug products submitted to the Miscellaneous External Panel (47 FR 39436 at 39439), but the Panel did not review or classify individual ingredients. Peruvian balsam was reviewed by the Hemorrhoidal Panel as a topical wound-healing agent (45 FR 35576 at 35654). That Panel concluded that Peruvian balsam was safe in concentrations up to 3 percent, but effectiveness in relieving anorectal symptoms such as burning, pain, itch, or swelling, or as a wound healing agent, had not been demonstrated. The Panel recommended Category III status for use in anorectal drug products.

The agency has evaluated the submissions and notes, as stated in one submission (Ref. 3), that the ingredient in the diaper rash products is not Peru balsam (which was evaluated by the Hemorrhoidal Panel), but is Peru balsam oil, a purified Peru balsam prepared by extraction with volatile solvents or distillation from balsam of Peru (Ref. 6).

The safety data in the submissions include a patch test performed on 200 infants with a cream product containing Peru balsam oil (Ref. 1). However, the concentration of Peru balsam oil in the cream product was not provided. The patch test showed no evidence of primary irritation or allergenicity. Fifty of the infants were re-tested and no secondary allergenicity was observed.

An acute dermal toxicity study involved a single 24-hour application of Peru balsam oil (2 g/kg) to the clipped, abraded, abdominal skin of 10 rabbits, (Ref. 3). No evidence of toxicity from percutaneous absorption and no abnormalities at necropsy were observed. A single-dose (5 g/kg) oral toxicity study was conducted on 10 albino male rats. The rats were observed on the day of the test and daily for 14 days (Ref. 3). Ten deaths occurred 3 to 24 hours after dosing; lethargy, catalepsy, loss of righting reflex, and slow respiration preceded the deaths.

To evaluate Peru balsam oil for systemic toxicity, an acute dermal toxicity study was conducted on 12 albino rabbits (Ref. 3). The test material was applied to the clipped, intact, and abraded skin areas (backs of the animals) and the area was covered with a snug-fitting rubber sleeve for 24 hours. The animals were divided into three groups of four animals each, and dose levels of 2.0 mL, 3.9 mL and 6.0 mL per kg of body weight were used. After the 24-hours exposure, the sleeves were removed, and the skin reactions were recorded. The animals were wiped down and observed for 14 days. There was no erythema or edema at the end of the 24-hours contact and during the 14 days of observation. No toxic effects and no significant changes in hematogram values were observed. Maximization tests were done on 25 healthy males to determine the contact-sensitizing potential of Peru balsam oil (Ref. 3). The Peru balsam oil was applied under occlusion to the same sites on the volar forearms for five alternate-day 48-hour periods, after pre-treatment for 24 hours with 5 percent aqueous sodium lauryl sulfate under occlusion. After a 10-day rest period, a challenge patch was applied under occlusion to fresh sites for 48 hours, preceded by a 1-hour application of 10 percent aqueous lauryl sulfate under occlusion. No contact-sensitization occurred in any of the individuals tested. Although the concentration of the Peru balsam oil used in these tests was not stated, the studies indicate that it is

unlikely that Peru balsam oil at the concentration tested would present a danger of contact-sensitization in normal, intended use. Other information included in the Monographs on Fragrance Raw Materials (Ref. 6) indicates that Peru balsam and Peru balsam oil would be safe in the low concentrations present in these diaper rash drug products.

One clinical evaluation was included in the submission (Ref. 1) to support the effectiveness of Peru balsam oil for diaper rash use. During a 2-year span, a cream product was tested on 558 newborn infants with perianal and/or diaper dermatitis. The average stay of the infants in the hospital and treatment time was 5 days. The dermatitis cleared in 537 of the infants. However, the submission did not provide any information on the severity of the rashes, the frequency of application of the cream, or whether the 21 infants who did not respond became worse. There was no mention whether the study was controlled, i.e., whether there was an infant control group or a vehicle control. Further, the concentration of Peru balsam oil in the product was not stated. Therefore, this study is not sufficient to support the effectiveness of Peru balsam oil for the treatment and/or prevention of diaper rash.

Based on current information, Peru balsam oil is labeled as an inactive ingredient in the manufacturer's products as a fragrance at a 0.125-, 0.32-, and 1.5-percent concentration (Refs. 4 and 5). Based upon the Monographs on Fragrance Raw Materials (Ref. 6), the agency finds 0.125 and 0.32 percent concentrations of Peru balsam oil acceptable as a fragrance. However, the agency has concerns as to whether the 1.5 percent concentration in the ointment product has any active ingredient properties. The agency notes that the United States Dispensatory (Ref. 7) indicates that Peruvian balsam (Peru balsam) has a number of drug uses when applied topically in the form of an ointment or alcoholic solution. Peruvian balsam was once official in The National Formulary (Ref. 8). In addition, Peruvian balsam is currently marketed as an active ingredient in a 1.26- and a 1.8-percent concentration in topical anorectal drug products (Ref. 9). Further, testimonials from several physicians (Ref. 1) attribute superiority of the manufacturer's diaper rash product over other products to the Peru balsam contained in it. Based on the above and the description of Peru balsam oil as a purified form of Peru balsam (Ref. 6), the agency questions the inactive ingredient status of a 1.5-percent concentration of Peru balsam oil used as a fragrance in a diaper rash drug product. As a rule, an inactive ingredient should be used only at a level required to achieve its intended function in the product. The concentration in the manufacturer's ointment product is almost 5 times that used in its lotion product and is 12 times that used in its powder product (Ref. 4). The agency needs additional supportive evidence that a 1.5-percent concentration of Peru balsam oil does not have any active ingredient properties when used in a diaper rash drug product. Based on the information available at this time, the agency classifies Peru balsam and Peru balsam oil at concentrations up to 3 percent in Category III for use in OTC diaper rash drug products.

References

(1) OTC Volume 160041.
(2) OTC Volume 160088.
(3) OTC Volume 160421.
(4) Letter from E. Waxman, Macsil, Inc., to W. E. Gilbertson, FDA, February 5, 1968, LET00020, Docket No. 78N-0021, Dockets Management Branch.
(5) Current labeling for Balmex Ointment in OTC Volume 06DRSTFM, Docket No. 78N-021D, Dockets Management Branch.
(6) Opdyke, D.L.J., editor, "Monographs on Fragrance Raw Materials," Research Institute for Fragrance Materials, Inc., in OTC Volume 160421.
(7) Osol, A., and R. Pratt, editors, "Peruvian Balsam," in "The Dispensatory of the United States of America," 27th Ed., J.B. Lippincott Co., Philadelphia, p. 688, 1973.
(8) Feldmann, E.G., editor, "Peruvian Balsam," in "The National Formulary," 13th Ed., American Pharmaceutical Association, Washington, p. 536, 1970.
(9) Huff, B.B., editor, "Physicians Desk Reference for Nonprescription Drugs," 10th Ed., Medical Economics Co., Inc., Oradell, NJ, pp. 607 and 627, 1989.

S. Comments on Sodium Bicarbonate

26. One comment stated that it had submitted information on the safety and efficacy of baking soda (sodium bicarbonate) used as an external analgesic and as a skin protectant. Referring to FDA's decision, published in the tentative final monograph for OTC skin protectant drug products (48 FR at 6830; February 15, 1983), that transferred sodium bicarbonate from the rulemaking for OTC skin protectant drug products to the rulemaking for OTC external analgesic drug products, the comment stated the baking soda should be considered in both rulemakings.

At the time that the tentative final monograph for OTC skin protectant drug products was published, the agency had determined that, based on the claims for sodium bicarbonate currently in that rulemaking, the uses for sodium bicarbonate under consideration would be addressed more appropriately in the rulemaking for OTC external analgesic drug products. Now that the agency has reviewed the information on the use of sodium bicarbonate for the treatment and prevention of diaper rash, the agency has determined that the diaper rash uses of sodium bicarbonate should be included in the skin protectant rulemaking. Accordingly, as the comment requested, sodium bicarbonate is now being considered in both rulemakings. (See also comment 27 below.)

27. One comment requested that sodium bicarbonate be classified in Category I for the treatment of diaper rash. The comment asked that data on sodium bicarbonate previously submitted to the Miscellaneous External Panel (Ref. 1) and to the rulemaking for OTC skin protectant drug products (Refs. 2 and 3) be considered along with the supplementary information submitted (Refs. 4 and 5) to demonstrate that sodium bicarbonate has been used and marketed for many dermatological conditions including diaper rash. The comment included a "dermatological summary of baking soda" (sodium bicarbonate) (Ref. 6) which contained references in the medical literature on the topical use of sodium bicarbonate (e. g., as a powder and in a bath) in a number of dermatological conditions.

The comment noted that, although sodium bicarbonate has not been the subject of double-blind clinical trials (a concept of relatively recent development, circa 1952), it has been used for a long time for its effectiveness in the treatment of a variety of skin conditions (Ref. 6). It is recommended by physicians and cited in medical literature. The basis of its efficacy is not completely understood. One mechanism of action to explain the topical effect of sodium bicarbonate is that it, as well as other mild alkali, softens the epithelial surface, skin, or mucous membranes resulting in a reduction of irritation when the skin is subject to a variety of irritants (Refs. 6 and 7). Urine and feces are irritating to the skin of infants when they are kept in close contact with the skin by diapers.

The Topical Analgesic Panel reviewed and classified sodium bicarbonate as safe and effective for use as a skin protectant (43 FR 34640). That Panel concluded that sodium bicarbonate is safe for use as a skin protectant with no age or concentration limits. However, that Panel did not review sodium bicarbonate for any diaper rash uses, and diaper rash was not included in the tentative final monograph for OTC skin protectant drug products (48 FR 6820; February 15, 1983). In addition, the

agency did not include sodium bicarbonate in the tentative final monograph for OTC skin protectant drug products because the indications submitted up to that time for products containing sodium bicarbonate were very similar to indications being evaluated for OTC external analgesic drug products (e.g., for the temporary relief of pain and itching due to minor burns, sunburn, * * * insect bites, and minor skin irritations"). Accordingly, sodium bicarbonate was transferred to the rulemaking for OTC external analgesic drug products. (See comment 33 at 48 FR 6830.)

The agency has reviewed the comments as well as other information available on sodium bicarbonate and is aware of one report of an adverse reaction in a 4-month-old infant after treatment of diaper rash with sodium bicarbonate (Ref. 8). The adverse reaction report states that liberal amounts of sodium bicarbonate and petrolatum had been applied to a severe diaper rash at every diaper change for more than a week. Physical examination showed a diffuse erythematous rash with large areas of denuded skin extending over most of the diaper area. The infant experienced hypokalemic metabolic alkalosis which the authors attributed to excessive sodium bicarbonate absorption from the baking soda that was applied to the diaper rash. The infant recovered completely following discontinuation of sodium bicarbonate treatments.

In the absence of supportive data, the agency is concerned about repetitive application of sodium bicarbonate powder to the diaper area for a prolonged period of time. The agency acknowledges that the Topical Analgesic Panel concluded that a 1-to-100 percent sodium bicarbonate preparation was safe for topical use on infants (43 FR 34628 at 34640). However, in evaluating the uses described by the Panel, the agency notes that the Panel was primarily considering limited application for short-term relief, *e.g.*, use in a bath or in the form of a moist paste or a solution. Limited application such as use in an occasional bath appears to present much less of a safety problem than repetitive application to the diaper area of an infant.

The agency has reviewed the references submitted by the comment; they state that the most common method of use of sodium bicarbonate for rashes is in solution as a bath, not as a powder. Weinberg and Hoekelman (Ref. 9) prescribe application of aqueous solutions in the form of baths, soaks, or wet dressings for their anti-inflammatory and drying actions. The authors include sodium bicarbonate among the substances commonly added to make the solutions. A marketed product containing sodium bicarbonate provides directions for emollient baths to relieve skin irritations (Ref. 1). Regarding the use of sodium bicarbonate for such baths, the submission (Ref. 1) cites the Merck Manual (Ref. 10) as recommending that 8 ounces of sodium bicarbonate be dissolved in about 30 gallons of warm water and that the patient should remain in the bath for 10 to 30 minutes or longer. The skin should be patted dry rather than rubbed so that a thin film of the drug remains on the skin. Other submitted data (Ref. 6) indicated that although there is variation regarding the recommended or optial concentration of sodium bicarbonate for baths and solutions, a range of 1 to 5 percent would encompass most of the concentrations.

Although a sodium bicarbonate bath may be useful in alleviating mild cases of irritation resulting from diaper rash, the data submitted by the comment do not contain any information or studies specific for diaper rash. Information is needed to show that sodium bicarbonate acts to treat or prevent diaper rash. Softening and soothing the skin, the actions described by the comment for sodium bicarbonate baths, are cosmetic claims. Further, the agency is unaware of any sodium bicarbonate product labeled for diaper rash bearing complete indications, directions, and warnings. The agency believes the information submitted is not adequate to show the safety and effectiveness of sodium bicarbonate, used as a bath or as a powder, for the treatment or prevention of diaper rash. Accordingly, the agency is classifying sodium bicarbonate in Category III for safety and efficacy for diaper rash.

References

(1) OTC Volume 160032.
(2) Comment C00027, Docket No. 78N-0021, Dockets Management Branch.
(3) Comment C00050, Docket No. 78N-0021, Dockets Management Branch.
(4) Comment C00047, Docket No. 78N-0301, Dockets Management Branch.
(5) Comment C00085, Docket No. 78N-0301, Dockets Management Branch.
(6) Eisenstat, B. A., "Dermatological Summary of Baking Soda," unpublished study, pp. 1–7, October 7, 1963.
(7) Sollmann, T., "A Manual of Pharmacology and its Applications to Therapeutics and Toxicology," 7th Ed., W. B. Saunders Co., Philadelphia, p. 121, 1948.
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(9) Weinberg, S., and R. A. Hoekelman, "Dermatology for the Primary Care Practitioner," McGraw-Hill, New York, p. 112, 1978.
(10) Lyght, C. E., editor, "The Merck Manual," 9th Ed., Merck and Co., Rahway, NJ, p. 1756, 1956.

T. Comments on Talc

28. Two comments requested Category I status for talc for the treatment and prevention of diaper rash. The comments noted that talc was among a number of ingredients contained in marketed products for diaper rash that had not been referred to any advance notice of proposed rulemaking. The comments stated that talc, which has a long record of safe and effective use on infants skin, should be referred to the skin protectant rulemaking because of its barrier like action, water insolubility, and emollience. The comments concluded that talc acts as an effective barrier to irritants that cause common diaper rash.

The agency agrees with the comments that talc should be considered for inclusion in the skin protectant rulemaking based on its physical properties. In the reopening of the administrative record for OTC skin protectant drug products, the Miscellaneous External Panel presented its conclusions and recommendations on OTC drug products containing skin protectant ingredients for the treatment and prevention of diaper rash. Talc was included in the list of ingredients in marketed products submitted to that Panel (47 FR 39436 at 39439). The Panel stated that most diaper rash treatments, e.g., talc and zinc oxide ointment and paste, help by protecting the skin, acting as a physical barrier to irritants, and absorbing or adsorbing moisture. The Panel discussed talc at its meetings on April 3, 1977 (Ref. 1) and June 5, 1977 (Ref. 2) and determined that talc was an adsorbent to be used on skin areas of excess moisture and as an aid in the prevention of skin chafing, diaper rash, and heat rash. The Panel decided that talc should be Category I for use on intact skin with the following labeling: "Indications: For use as an absorbent on skin areas of excess moisture and as an aid in prevention of skin chafing, diaper rash, and heat rash; Warning: Do not use on broken skin, rashes, or open wounds," (Refs. 2 and 3). At its forty-first meeting on October 5 and 6, 1980 (Ref. 4), the Panel reaffirmed its previous decision that talc should be classified Category I for safety and effectiveness for the prevention of diaper rash. Nevertheless, in its final

recommendations to the agency, the Panel did not classify any ingredients for use in diaper rash.

A standard text book reference submitted by one of the comments (Ref. 5) included talc among the powdered agents used in treating diaper rash. The text describes talc as a natural hydrous magnesium silicate that allays irritation, prevents chafing, and absorbs sweat; it is similar to ointments and creams in that it adheres well to the skin. Talc was also identified as an ingredient in many of the products marketed for diaper rash that were listed in the text.

At the 1951 Round Table Discussion of the American Academy of Pediatrics (Ref. 6), talc was approved in the routine care of the newborn because it does not plug the pores. One standard text (Ref. 7) stated that talc remains the most important constituent of baby powder because it has excellent slip characteristics, good adhesion to the skin, and acts as a lubricant where skin surfaces are in apposition, as in the diaper area (buttocks and groin), and because it is water repellent and prevents chafing. Other authors discuss the use of talc for the treatment (Refs. 5, 8, and 9) as well as for the prevention (Ref. 10) of diaper rash.

Based on an analysis of the above information and the long marketing history of talc in diaper rash drug products, the agency tentatively concludes that talc can be generally recognized as safe and effective for the prevention and treatment of diaper rash. Although the Panel recommended talc only for the prevention of diaper rash, the agency believes talc can be used for the treatment of diaper rash provided it contains the same warning, i.e., not to use on broken skin, as the Panel recommended for prevention of diaper rash (Ref. 3). This warning is necessary because crusting, infection (Ref. 5), and skin granulomas (Refs. 11 and 12) have been known to result when talc and other powders (Ref. 13) are applied to broken skin.

While recognizing extensive use of powdered dosage forms for many years, the agency believes that an additional warning for diaper rash drug products in a powdered dosage form is needed because of numerous reported incidences of accidental inhalation of baby powders appearing in the literature (Refs. 5, 11, 12, and 14 through 19). Smith (Ref. 5) states that powders should be used cautiously and parents should be instructed to apply these powder products carefully to prevent the infant from inhaling the powder which may be harmful and could lead to chemical pneumonia. One study (Ref. 14) showed that baby powder inhalation occurs more frequently in children under 5 years of age than previous literature indicates. An age analysis of 34 cases showed that 55 percent of the children were under 1 year of age, 41 percent were in their second year, and 4 percent were over 2 years of age. The study showed that 73 percent of the children were being changed at the time inhalation occurred, and that one child developed aspiration pneumonia. In a later talc-aspiration report (Ref. 17), another child required ventilation on a respirator for several days. Moss (Ref. 18) mentioned that 50 cases of talcum powder aspiration are reported annually to one poison control center, but a survey of 100 mothers of children under 2 years of age indicated that 42 percent were unaware of the dangers if a child inhaled the powder. It appears that these cases have not been reported to the agency.

Several case histories of adverse reactions after inhalation of talcum powder are described in the literature. The youngest child was a 1-month old infant who went into cardiorespiratory arrest after powder was poured into her mouth and nose by a 3-year old sibling (Ref. 15). The infant received resuscitation and survived. Molnar, Nathenson, and Edberg (Ref. 16) reported that a 22-month old boy died of intractable cardiopulmonary failure, caused by respiratory distress and perioral cyanosis, 20 hours after inhaling talcum powder while playing with a container of the substance. Hughes and Kalmer (Ref. 11) reported that a 14-month old child developed severe respiratory distress after inhaling talcum powder when playing with the container, but recovered after treatment. Another report (Ref. 19) described five cases of children between 1 and 2 years of age who inhaled talcum powder. Three of these children died, even though they had received the recommended treatment of humidified oxygen in a tent, antibiotics, and epinephrine. The two survivors received corticosteroid drugs in addition to the other treatment.

Although talc has been implicated in these toxic episodes when aspirated accidentally or through misuse, the agency believes that talc can be labeled appropriately for safe OTC use. Therefore, the agency is proposing the following warnings for products containing talc: (1) "Do not use on broken skin." (2) "Keep powder away from child's face to avoid inhalation, which can cause breathing problems." (See also comment 7 above for discussion of directions for powder products.)

Although the Panel recommended that talc be Category I for the prevention of diaper rash, it did not recommend a safe and effective concentration range. None of the submissions to the Panel contained data regarding the concentration of talc in diaper rash products, and the comments did not provide any information on this subject. The agency has surveyed the marketplace and determined that most standard text books do not indicate a concentration range for talc in marketed diaper rash drug products. Only one of seven products containing talc used for diaper rash listed in the "Handbook of Nonprescription Drugs" (Ref. 5) provides its concentration (45 percent talc).

The agency is aware that up to 100 percent talc is used in some cosmetic products, e.g., dusting powders, and that consumers may use such products for preventing or treating diaper rash. Data submitted to the Miscellaneous External Panel (Ref. 20) on cosmetic talc indicated that with normal use it is not hazardous to health. Cosmetic talc should contain at least 90 percent platy talc (having flat as opposed to fibrous particles) that is free of detectable amounts of fibrous minerals, including asbestos. Cosmetic talc is not an allergen and does not alter the viability or phagocytic activity of pulmonary macrophages. Exposure of hamsters to cosmetic talc dust containing approximately 8 mg per cubic meter of respirable particles for periods of up to 2 and 1/2 hours per day for 300 days failed to produce any significant pulmonary or other pathological changes or differences in morbidity or mortality. The hamsters were exposed to a dust dose of up to 1,850 times the median human exposure. An epidemiological study of cosmetic talc millers who began their employment between 1921 and 1950 showed no increased incidences of death due to respiratory disease. The millers' exposure to talc dust was 384 times larger each day than a consumer's daily exposure to cosmetic talc powders.

The agency believes that products containing these higher concentrations of talc can be safely used on infants provided they contain the warnings discussed above. Therefore, the agency is tentatively proposing the concentration range for talc for use in diaper rash drug products at 45 to 100 percent and is inviting comments and data on this proposed concentration range and the proposed warnings.

Accordingly, the agency is tentatively classifying talc (45 to 100 percent) in Category I for use in the treatment and prevention of diaper rash with labeling

that includes the two warnings discussed above.

References

(1) Transcript of Proceedings of the Advisory Review Panel on OTC Miscellaneous External Drug Products, April 3, 1977, pp. 20–43, in OTC Volume 06DRSTFM, Docket No. 78N–021D, Dockets Management Branch.

(2) Transcript of Proceedings of the Advisory Review Panel on OTC Miscellaneous External Drug Products, June 5, 1977, pp. 22–46, in OTC Volume 06DRSTFM, Docket No. 78N–021D, Dockets Management Branch.

(3) Summary Minutes of the Eighteenth Meeting of the Advisory Review Panel on OTC Miscellaneous External Drug Products, June 5 and 6, 1977, Docket No. 78N–0021, Dockets Management Branch.

(4) Summary Minutes of the Forty-first Meeting of the Advisory Review Panel on OTC Miscellaneous External Drug Products, October 5 and 6, 1980, Docket No. 78N–0021, Dockets Management Branch.

(5) Smith, G.H., "Diaper Rash and Prickly Heat Products," in "Handbook of Nonprescription Drugs," 7th Ed., American Pharmaceutical Association, Washington, pp. 605–614, 1982.

(6) Osborne, E.D., et al., "Round Table Discussion: Pediatric Dermatology," American Academy of Pediatrics, 10:710–720, 1952.

(7) Barnett, G., "Baby Toiletries," in "Cosmetics—Science and Technology," 2d Ed., Wiley-Interscience, New York pp. 136 and 152, 1972.

(8) Brown, M.S., "Over-the-Counter Drugs for Skin Disorders, Part 3: Aids for Heat and Diaper Rash," Nurse Practitioner, July-August: 28–30,36, and 41, 1977.

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(10) Williams, M.L.K., "How I Treat Diaper Rashes," Medical Times, 108:50–53, 1980.

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(12) Wade, A., editor, Martindale, "The Extra Pharmacopoeia," 27th Ed., The Pharmaceutical Press, London, p. 455, 1977.

(13) Kelly, R., and P.E. Campbell, "Granuloma Glutaeale Infantum with Starch Granules in the Lesion," The Medical Journal of Australia, 2:438–439, 1973.

(14) "The Hazards of Baby Powder," Medical Science Bulletin—2, 4:2, 1981.

(15) Brouillette, F., and M.L. Weber, "Massive Aspiration of Talcum Powder by an Infant," Canadian Medical Association Journal, 119:354–355, 1978.

(16) Molnar, J.J., G. Nathenson, and S. Edberg, "Fatal Aspiration of Talcum Powder by a Child," The New England Journal of Medicine, 266:36–37, 1962.

(17) Mofenson, H.C., et al, "Baby Powder—A Hazard!", Pediatrics, 68:265–266, 1981.

(18) Moss, M.H., "Dangers from Talcum Powder", letter to the editor, Pediatrics, 43:1058, 1969.

(19) "Accidental Inhalation of Talcum Powder," British Medical Journal, 4:5–6, 1969.

(20) OTC Volume 160191.

U. Comments on Vitamins A and D

29. Two comments requested Category I status for vitamins A and D as ingredients in the skin protectant rulemaking for diaper rash drug products. The comments did not submit any data to establish safety and effectiveness, but argued that vitamins A and D have recognized properties of barrier-like action, water insolubility, and emollience. The comments concluded that these ingredients have a long history of use on infant skin and should receive favorable consideration as safe and effective skin protectants for the treatment and prevention of diaper rash because they act as an effective barrier to irritants that cause common diaper rash.

Note: "Vitamin D" was the name designated for this ingredient by the Panel in its statement. "Cholecalciferol" is the official title in the current edition of "USAN and the USP dictionary of drug names" (Ref. 1), and will be used in this document.

Vitamin A and cholecalciferol have not been classified as skin protectants in any rulemaking in the OTC drug review. The Hemorrhoidal Panel evaluated these ingredients as wound-healing agents in OTC anorectal drug products and classified them in Category III (45 FR 35576 at 35655 and 35656). That Panel advised that vitamin A is safe topically at an adult dosage of 1,710 International Units (IU) (0.5 mg) per dosage unit, not to exceed 10,000 IU (3.44 mg) per 24 hours and that cholecalciferol is safe topically at an adult dosage of 4.5 IU (0.00011 mg) per unit dose, not to exceed 27 IU (0.00066 mg) per 24 hours. That Panel also reviewed cod liver oil (which contains vitamin A and cholecalciferol) for use as a skin protectant and wound-healing agent and advised that cod liver oil is safe topically at an adult dosage not to exceed 10,000 IU vitamin A and 400 IU cholecalciferol per 24 hours and classified it in Category I as a skin protectant (45 FR 35630) and Category III as a wound healing agent (45 FR 35650). The Panel stated that the protectant effect of cod liver oil is attributed to the bland and soothing effect associated with its oily nature (45 FR 35630) and that no definitive clinical data support the effectiveness of vitamin A and cholecalciferol as wound-healing agents (45 FR 35656). In the tentative final monograph for OTC anorectal drug products, the agency agreed with the Panel's recommendations on vitamin A, cholecalciferol, and cod liver oil (53 FR 30756 at 30777).

Data on vitamin A and cholecalciferol as wound-healing agents were also submitted to the Miscellaneous External Panel. One manufacturer submitted data for a product containing in each ounce vitamin A and cholecalciferol equivalent to one ounce of cod liver oil (approximately 24,000 U.S.P. units vitamin A and 2,400 U.S.P. units cholecalciferol) in a vanishing cream base (Ref. 2). (One U.S.P. unit is identical to one IU (Ref. 3).) The submission was considered by the Panel in preparing its statement on OTC diaper rash drug products (47 FR 39436 at 39439), but the Panel did not classify any individual ingredients for this indication. The labeling states that the product is "for relief of chapped skin, diaper rash, wind burn and sunburn; and minor non-infected skin irritations." The directions for using the product to relieve minor skin irritations are "apply locally to unbroken skin with gentle massage or apply liberally to abraded skin surfaces where promotion of epithelization is desired."

The submission includes one article on diaper rash and prickly heat (Ref. 4) which states that preparations containing vitamin A and cholecalciferol were reported, in older literature, to promote healing and stimulate granulation, but that "it is difficult to substantiate this in modern literature." The submission also contains a published report of the successful use of a cod liver oil ointment in treating atopic eczema on a 15-month old boy.

The agency finds the submitted data are insufficient to support the use of vitamin A and cholecalciferol for diaper rash indications. The efficacy data pertain mainly to wound healing in adult subjects suffering from burns and other dermatologic conditions and to the use of vitamin A to treat acne in adolescents. There are no studies on the use of vitamin A or cholecalciferol for the treatment of diaper rash in infants and young children.

In this tentative final monograph, the agency is proposing a Category I classification of cod liver oil as a skin protectant ingredient for use in the treatment and prevention of diaper rash. (See comment 14 above.) This classification is based on the long marketing history of the safe use of cod liver oil as an ingredient in topical products used on infants and children and the Hemorrhoidal Panel's Category I recommendation of cod liver oil as a protectant ingredient. However, there is insufficient evidence to support the effectiveness of either vitamin A or cholecalciferol for use as an individual active ingredient or in combination other than as a component of cod liver oil in the treatment of diaper rash. The available data on the two ingredients

pertain to their use as wound-healing agents on adolescents and adults, not on infants and young children. These studies fail to establish that vitamin A and cholecalciferol contribute to wound healing. Further, the agency is not aware of any data that support the safety and effectiveness of wound-healing agents as components of OTC diaper rash drug products. The claim "promotes healing" has not been demonstrated in clinical studies for any ingredient contained in OTC diaper rash drug products.

Accordingly, the agency concludes that further data are needed to establish the effectiveness of vitamin A and cholecalciferol when used individually or in combination other than as a component of cod liver oil in OTC diaper rash drug products and classifies these ingredients in Category III for diaper rash use.

References

(1) "USAN and the USP Dictionary of Drug Names," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 122, 1989, s. v. "Cholecalciferol."

(2) OTC Volume 160028.

(3) "The United States Pharmacopoeia XXII—The National Formulary XVII," United States Pharmacopeial Convention, Inc., Rockville, MD, p. 1473, 1989.

(4) Sadik, F., "Diaper Rash and Prickly Heat," in "Handbook of Non-Prescription Drugs," 1971 Ed., American Pharmaceutical Association, Washington, pp. 171–176, 1971.

V. Comment on Zinc Oxide

30. One comment requested that zinc oxide at an allowable dosage limit up to and including 40 percent be classified in Category I as a skin protectant for diaper rash. The comment noted that the Topical Analgesic Panel had recommended a dosage range of 1 to 25 percent for zinc oxide in its report on OTC skin protectant drug products (43 FR 34628 at 34648). The comment stated that data were submitted to the Miscellaneous External Panel to support the use of zinc oxide as a skin protectant in concentrations up to and including 40 percent (Ref. 1). The comment added that the minutes of the fourteenth meeting (November 12–13, 1976) of the Miscellaneous External Panel indicated that the Panel had recommended an upper limit of 40 percent for zinc oxide as a skin protectant (Ref. 2).

The Topical Analgesic Panel did not receive any data demonstrating the safety and effectiveness of zinc oxide as a skin protectant in concentrations above 25 percent. Based on the data available to it, that Panel recommended zinc oxide at a concentration up to and including 25 percent as a Category I skin protectant ingredient for use on infants, children, and adults (43 FR 34641). The agency concurred with this recommendation in its tentative final monograph for OTC skin protectant drug products (48 FR 6820 at 6832).

The data submitted to the Miscellaneous External Panel included information on an ointment containing 40 percent zinc oxide and 13.56 percent cod liver oil in a petrolatum base evaluated for the prevention or treatment of diaper rash. The submission for this product was referenced in appendix A to that Panel's minutes of its fourteenth meeting (Ref. 2). At that meeting, the Panel decided that zinc oxide at a concentration of 3 to 40 percent should be recommended as Category I for use as a protective, absorbent, and astringent. However, the Panel did not include this recommendation in its final report on OTC diaper rash drug products. The Panel chose instead to recommend the inclusion of zinc oxide for diaper rash claims in the rulemaking for OTC skin protectant drug products, but did not discuss a specific concentration for this or any other ingredient.

The submission includes an unpublished study using the ointment containing 40 percent zinc oxide (Ref. 3). In the study, 97 infants, age 12 months or younger, were assigned to one of two treatment groups. Group one received the ointment on an as needed basis. Group two received the same ointment six times a day. Biweekly examinations for diaper rash were made of the diaper area of each infant. Rashes were scored on a scale of zero (normal or no more than slight dryness) to four (pustules, excoriations, or other severe irritative conditions). The mothers were instructed to make no changes in any other aspect of baby-care except that no medicated lotions or powders were to be used. Neither group showed any evidence of an increase in irritation.

The submission also included an incomplete clinical study using the product for the treatment of diaper rash (Ref. 4). The study was considered incomplete because at the time it was submitted data were available for only thirty-five of the fifty cases discussed in the study. The additional data were submitted at a later date (Ref. 5). The study was completed on forty-five infants. Infants with an uncomplicated diaper rash were treated on either the right or left side of the diaper area with the product for 24 hours. The diaper area was divided into left and right sides with the umbilicus or vaginal folds anteriorly and the gluteal folds posteriorly designated as anatomic dividing lines, allowing each infant to be tested with the ingredient and compared with the control. The untreated side of the diaper area was permitted to be treated only with unmedicated talcum powder or bland soap. The severity of the rash was graded by a physician prior to initiation and at the completion of treatment using a scale of zero (absent) to five (severe). At the end of the treatment period, the physician also evaluated the difference between the treated and untreated side using a five-point scale ranging from one (much better) to five (much worse). The mothers also scored the severity of the rash at the initiation of treatment and at every diaper change on a scale from zero (none) to three (severe). The data showed that the treated side was significantly better than the untreated side on every measure. The only exceptions are the mothers' rating of severity of rash during the first eight hours after treatment began. No adverse reactions to the product were noted by either physician or mothers during the course of the study, and in no case was the treated side worse than the untreated side.

The agency believes that the studies discussed above support the safe use of 40 percent zinc oxide in an ointment dosage form. A review of the adverse reaction reports for zinc oxide and the 40 percent zinc oxide ointment product included in the agency's adverse drug reaction reporting system revealed only two minor adverse reactions (rash) to the ointment product (Ref. 6).

The agency has also considered the evaluation of zinc oxide done by the Miscellaneous External Panel at its fourteenth meeting (Ref. 2). That Panel concluded that zinc oxide crystals are not absorbed through the skin and pose no threat of systemic absorption with dermal application. Based on this conclusion, the Panel recommended no limit on zinc oxide dosage to body surfaces. However, the agency evaluated the nine OTC submissions cited in appendix A to the Panel's minutes and did not find any data to support the safe use of 40 percent zinc oxide on infants in other than an ointment dosage form. Because the agency is not aware of any data supporting the safe use of zinc oxide on infants at a concentration above 25 percent in any other dosage form, the agency is proposing to limit concentrations above 25 percent up to 40 percent zinc oxide to use in a suitable ointment dosage form as a Category I skin protectant ingredient for the prevention or treatment of diaper rash. Zinc oxide in 1 to 25 percent concentrations, as currently proposed in § 347.10(m), may be used in any

appropriate dosage form for a product intended to prevent or treat diaper rash.

References

(1) OTC Volume 160021.

(2) Summary Minutes of the Panel on Review of Miscellaneous External OTC Drug Products, Fourteenth Meeting, November 12 and 13, 1976, Docket No. 78N–0021, Dockets Management Branch.

(3) "Efficacy and Safety on Baby Ointment #0E14 for Leeming/Pacquin," draft of unpublished study, in OTC Volume 160021.

(4) "Desitin in the Treatment of Diaper Rash," Clinical Protocol Associates, Inc., draft of an unpublished study, in OTC Volume 160021.

(5) Comment No. C00058, Docket No. 78N–0021, Dockets Management Branch.

(6) Print-out of Adverse Drug Reactions to Cod Liver Oil, Zinc Oxide, and Desitin, January 17, 1990, Food and Drug Administration Adverse Drug Reaction Reporting System, in OTC Volume 06DRSTFM, Docket No. 78N–021D, Dockets Management Branch.

W. Comments on Drug Combinations

31. Two comments recommended a combination policy for diaper rash drug products similar to that contained in the Panel's proposed monograph for OTC skin protectant drug products (43 FR 34628 at 34631). The comments requested that a combination of two or more skin protectant ingredients be classified as Category I for treatment or prevention of diaper rash under the following conditions: (1) Each of the ingredients is present in sufficient quantity to act additively or by summation to produce the claimed therapeutic effect when present within the safe and effective concentration range specified for each ingredient in the monograph; (2) the ingredients do not interact with each other to reduce the effectiveness of any other ingredient(s) by precipitation, changes in acidity or alkalinity, or in some other manner that reduces the claimed therapeutic effect. One of the comments added that each ingredient or combination of ingredients must meet an appropriate level of effectiveness in treating or preventing diaper rash.

The Topical Analgesic Panel recommended that two or more skin protectant active ingredients may be combined provided the ingredients meet the conditions which are enumerated above, the partition of the active ingredients between the skin and the vehicle in which they are incorporated is not impeded, and the therapeutic effectiveness of each remains as claimed or is not decreased (43 FR 34631). In the tentative final monograph for OTC skin protectant drug products, the agency proposed various combinations of skin protectant active ingredients that varied depending on the labeling claims for the combinations. (See proposed § 347.20 at 48 FR 6832.) The use of skin protectant ingredients for the treatment and prevention of diaper rash was not discussed in that tentative final monograph, but is discussed in comment 8 above. In that comment, the agency states that an indication for treatment or prevention of diaper rash is being provided for those Category I skin protectant ingredients in § 347.10 that do not have a lower age limitation and that have a marketing history for such use, i.e., allantoin, calamine, dimethicone, kaolin, petrolatum, white petrolatum, and zinc oxide. (See detailed discussion in comment 8 above.) In addition, in this document, the agency is proposing the inclusion of additional ingredients in § 347.10 that were not included in the skin protectant tentative final monograph, i.e., cod liver oil, lanolin, mineral oil, talc, and topical starch. Some of these ingredients, such as cod liver oil and lanolin, are classified in Category I only when present in a combination product. (See comments 14 and 21 above.) Accordingly, the agency is proposing in this document to add new § 347.20(e) to the skin protectant tentative final monograph, to read as follows: "Any two or more of the ingredients identified in § 347.10 (a), (c), (e), (g), (h), (j), (m), (n), (o), (p), (q), (r), and (s) may be combined provided the combination is labeled according to § 347.50(b)(5) and provided each ingredient in the combination is within the concentrations specified in § 347.10."

32. One comment requested that the combination of a Category I antimicrobial agent and one or more Category I skin protectants be recognized as an acceptable Category I combination for the treatment and prevention of diaper rash. The comment contended that the antimicrobial agent would help reduce the level of harmful bacteria present in the diapered area and thus aid in the prevention and treatment of diaper rash. The comment suggested that indications for such a combination should include statements such as: "Helps kill germs associated with diaper rash" and "Helps kill germs that may aggravate diaper rash." Another comment mentioned that some diaper rash drug products contain ingredients that have not been classified in the skin protectant rulemaking, e.g., antimicrobials, antifungals, or external analgesics. The comment recommended that such ingredients must, first of all, have a record of safety for use on infants' skin and, secondly, when used in combination with a skin protectant for diaper rash, the combination product should meet the criteria established under each appropriate monograph.

The agency agrees with the second comment that each specific combination of one or more skin protectant ingredients and an ingredient other than a skin protectant must have established safety and effectiveness when used to treat or prevent diaper rash. As discussed elsewhere in this issue of the **Federal Register**, there are no antimicrobial, antifungal, or external analgesic active ingredients classified as Category I for the treatment and prevention of diaper rash.

Based on the status of the ingredients proposed in the notices of proposed rulemaking for OTC diaper rash drug products published in this issue of the **Federal Register**, combinations of a skin protectant active ingredient with other active ingredients are classified as follows: a skin protectant ingredient combined with another skin protectant ingredient, Category I; a skin protectant ingredient combined with an antimicrobial ingredient, Category III; a skin protectant ingredient combined with either an antifungal ingredient or an external analgesic ingredient, Category II.

33. A submission to the Miscellaneous External Panel (Ref. 1) included data to support the safety and effectiveness of a diaper rash cream containing a combination of dl-methionine,[1] cysteine hydrochloride, benzethonium chloride, talc, and a protein hydrolysate containing the amino acids 1-leucine, 1-isoleucine, 1-methionine, 1-phenylalanine, and 1-tyrosine. The submission was included in the list of submissions received by the Panel in its statement on OTC diaper rash drug products (47 FR 39439). The Panel considered the submission in preparing its statement but did not classify any individual ingredients for this indication.

The labeling for the product included in the submission stated that the product contained a germicide to help prevent irritation and amino acids to promote healing. Elsewhere in this issue of the **Federal Register**, the agency states its tentative conclusions on the use of antimicrobial ingredients for the treatment or prevention of diaper rash. In comment 32 above, the agency discusses combination products containing antimicrobial ingredients and skin protectant ingredients used for diaper rash. Talc is discussed in comment 28 above. The agency is addressing the use of amino acids in the

[1] Racemethionine is the official title in the 1989 edition of "USAN" and USP dictionary of drug names" and will be used in this document.

treatment or prevention of diaper rash in this comment.

The manufacturer cited the role of the amino acids methionine and cysteine and the protein hydrolysate in promoting wound healing as part of the basis for the formulation of the product. The manufacturer submitted in vitro data and animal studies to support the use of the amino acids methionine and cysteine in the regeneration of wound tissues and to show the effect of dietary deprivation of these amino acids on wound healing (Refs. 2 through 6). Based on animal studies by Edwards (Ref. 7) and other animal studies by Intoccia, Walsh, and Bogner (Ref. 8), the manufacturer concluded that both methionine and cysteine are relatively well absorbed following topical administration and are incorporated into body tissues.

The agency has reviewed the submission and concludes that the data are not sufficient to support a Category I classification for the topical use of amino acids to treat or prevent diaper rash. Susca and Geuting (Ref. 9) evaluated the total product, consisting of methionine, cysteine, protein hydrolysate, benzethonium chloride, and talc in a cream base, for the treatment of diaper rash against a placebo, consisting of the cream base without the active ingredients. Prior to using the product on infants with diaper rash, the authors tested the product for sensitizing potential by applying it to the arms and forearms of 25 infants and 25 children. On 20 occasions, the product was allowed to remain on the skin for at least 4 hours. No irritation was evident after 24 or 48 hours and no other side effects occurred. The agency notes that the article does not state whether or not occlusion was used to maintain the product in close contact with the skin. Therefore, the agency is not able to make any conclusions about the sensitizing potential of the product under the occlusive conditions found in the diaper area.

After the test for sensitizing potential was completed, the total product was applied to 52 infants and children (ranging in age from 6 days to 24 months) with diaper rash. Forty-seven of the children in the test group had a moderate degree of diaper rash characterized by marked erythema and papulovesicular lesions, two had a mild rash with few or no lesions, and three had severe rashes with ulcerations. The placebo group consisted of 50 children. No details concerning the makeup of this placebo group or the severity of the rashes in this group were provided. In 50 of the 52 subjects in the test group, the rashes receded after 48 hours and cleared after 5 days. The control group showed an overall lack of response to the placebo with few children showing slight improvement. Specific details on the response of the placebo group are not provided. No side effects were noted in any of the subjects in the study.

Christian and Gonzalez (Ref. 10) compared the same cream product for the treatment of diaper rash against a placebo consisting of fatty acid esters in a stabilized emulsion with a neutral pH. In this study, 36 infants (ranging in age from 5 days to 2 years) with diaper rashes ranging from mild to severe were treated with the cream product and 29 infants in the control group received the placebo. Both groups were balanced with regard to the severity of their rashes. In the placebo group, 13 cases showed complete or almost complete clearing, 8 cases showed moderate improvement, and 5 showed slight improvement, while 3 infants showed no improvement. In the test group, 30 cases showed complete or almost complete clearing while 6 showed moderate improvement. All the subjects in the test group showed some improvement. However, because the placebo used was not the cream base without the active ingredients, no conclusions regarding the contribution of the active ingredients to the effectiveness of the product can be made.

While the studies discussed above provide some evidence of the safe and effective use of the total cream product for the treatment of diaper rash, the data do not show (1) contribution of the individual amino acids to the effectiveness of the product, (2) contribution of the combination of amino acids to the effectiveness of the product, (3) contribution of the protein hydrolysate to the effectiveness of the product, and (4) whether the effectiveness shown resulted from the amino acid components of the product, from the talc, or from the antimicrobial benzethonium chloride. Therefore, the agency is classifying the individual ingredients racemethionine and cysteine hydrochloride; a protein hydrolysate composed of 1-leucine, 1-isoleucine, 1-methionine, 1-phenylalanine, and 1-tyrosine; and the combination of these ingredients in Category III for safety and effectiveness for the treatment or prevention of diaper rash.

References

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(8) Intoccia, A.P., J.M. Walsh, and R.L. Bogner, "Absorption and Incorporation of Methionine-S^{35} into Hair," Journal of Pharmaceutical Sciences. 53:372–375, 1964.

(9) Susca, L.A., and B.G. Geuting, "Treatment of Diaper Rash," New York State Journal of Medicine, 60:2858–2862, 1960.

(10) Christian, J.R., and F. Gonzalez, "Topical Treatment of Acute and Chronic Diaper Rash with Amino Acid Creme," Clinical Medicine, Vol. 8 (original article), 1961.

X. Comment on Testing

34. One comment suggested that the agency consider establishing a standard by which the effectiveness of diaper rash products may be determined for a claimed therapeutic benefit. The comment suggested a rating system, similar to the one that a panel recommended for sunscreen drug products at 43 FR 38265, as a way of measuring the levels of skin protection afforded by various diaper rash compositions. The comment recommended the following specific factors that might be considered in establishing the rating system: an ingredient's or combination of ingredients' tenacity and ability to adhere to the distressed diaper area, the degree of repellancy or insolubility afforded by a preparation, the viscosity or thickness of a preparation, intervals required between applications, and other physical and chemical properties of the preparation. The comment noted that while no research has specifically addressed these factors in connection with diaper rash preparations, studies have been made of the general properties of occlusive barrier ointments. The comment provided two published studies (Refs. 1 and 2) regarding the protectant characteristics of ointments which it felt offered a possible approach to the measurement of levels of skin protection afforded by diaper rash preparations. The comment

also proposed two clinical protocols to determine the effectiveness of diaper rash preparations: one for the prevention of diaper rash and the other for the treatment of existing diaper rash (Ref. 3).

The rating system for sunscreen drug products referred to by the comment was recommended by the Topical Analgesic Panel. That Panel stated that the extent of erythemal response to the sun is a function of skin color and identified five skin types that vary in their erythemal response to the sun (43 FR 38206 at 38210 and 38213). The "Sun Protection Factor" (SPF) was recommended by the Panel as a practical guide to aid the consumer in selecting the most suitable sunscreen for the level of sun protection suitable for his or her purposes. The Panel stated that the majority of consumers who use sunscreens have no pathological conditions, but desire to prevent a painful sunburn. The Panel further stated that individuals who are particularly susceptible to the immediate and cumulative effects of sunlight exposure should protect themselves from the harmful ultraviolet radiation from the sun (43 FR 38209). However, in the case of diaper rash, the agency believes that the consumer desires one level of protection, the complete protection of the infant's skin, whether dealing with a preexisting diaper rash or preventing a future rash. Therefore, the agency does not believe that a rating system, as suggested by the comment, would serve a useful purpose for OTC diaper rash drug products.

The agency has reviewed the two published studies (Refs. 1 and 2) submitted by the comment. The studies discuss a method for determining the protection afforded skin surfaces by various ointments. The basis for the method is the reaction of non-specific esterases found on the skin with 1-naphthylacetate to form 1-naphthol and acetic acid. The 1-naphthol formed by the reaction then can couple with the dye diazo blue B to form an azodye that stains the skin surface. Steigleder determined that this reaction is inhibited when an incubation medium containing 1-naphthylacetate and diazo blue B cannot make contact with the skin, *e.g.*, when the skin surface is covered with a protective ointment (Ref. 1).

In the other study, a glass chamber filled with an incubation medium containing 1-naphthylacetate and diazo blue B dye was placed on the skin surface of the forearms of 86 subjects following the application of various ointments. In each case, a control reaction was done on untreated skin of both forearms. The ointments were applied in two different ways: a "thin" application and a "thick" application (one to two millimeters thick). In addition, in some cases a thin layer of ointment was applied and wiped off, and in some other cases a thick layer of ointment was applied and rubbed into the skin 20 times. The glass chamber with the incubation medium was placed on the skin surface either immediately after the ointment was applied or following intervals varying between 30 and 120 minutes. Incubation times varied between 10 and 30 minutes.

The method discussed in the study measures the skin protection against water that is afforded by ointments in an almost static situation. However, diaper rash products are subject to exposure to urine and feces, increased temperature and humidity, and mechanical removal by friction. The agency believes that ointments tested by the proposed method would be substantially more effective than they would be under actual use conditions.

Further, the agency finds that the authors considered their method to be of limited usefulness. The authors stated that a detergent may remove esterases from the skin surface, and this test method should be avoided whenever substances are applied to the skin which inhibit the esterases or interfere with the formation of the azodye in the incubating medium. The agency also finds that this method, published over 25 years ago, does not appear to have gained general acceptance and usage in testing products for the degree of skin protection afforded. Therefore, the agency concludes that the method suggested by the comment would not be appropriate for establishing a rating system for diaper rash drug products.

The agency has reviewed the two proposed clinical protocols and finds them inadequate in several areas. In the protocol for treatment of diaper rash, no information is given about diaper rash variability in the infants to be studied, and the degree of difference between the effects of the treatments that will be considered clinically significant is not stated. Therefore, it cannot be determined whether a sample size of 25 infants is sufficient for the study. In addition, the proposed age span (0–24 months) does not take into consideration the difference in body chemistry among infants in this range of ages. An age range of 2 to 4 months may be more appropriate for a study of this type. Also, no consideration was given to the various types of diapers that may be used, the protocol lacked proper blinding, and specific instructions to the parents as to cleansing agent to use and amount of the product to apply were not provided. These inadequacies also apply to the proposed test for the prevention of diaper rash. In addition, it is unclear how this test will show effective "prevention" because the test subjects include infants who already have diaper rash. Further, the rationale for the use of a two-treatment, two-period crossover design was not presented.

The agency is not proposing specific testing guidelines in this document. In revising the OTC drug review procedures relating to Category III, published in the Federal Register of September 29, 1981 (46 FR 47730), the agency advised that tentative final and final monographs will not include recommended testing guidelines for conditions that industry wishes to upgrade to monograph status. Instead, the agency will meet with industry representatives at their request to discuss testing protocols. The revised procedures also state the time in which test data must be submitted for consideration in developing the final monograph. (See also part III, paragraph A. 2. below—Testing of Category II and Category III Conditions.)

References

(1) Steigleder, G.K., "A Method for Evaluating the Protection Afforded Skin Surfaces by Ointments," The Journal of Investigative Dermatology, 35:225–226, 1960.

(2) Steigleder, G.K., and W.P. Raab, "Skin Protection Afforded by Ointments," The Journal of Investigative Dermatology, 38:129–130, 1962.

(3) Comment No. C00030, Docket No. 78N–0021, Dockets Management Branch.

II. The Agency's Evaluation of the Submissions

Of the ingredients listed in the Miscellaneous External Panel's statement, the following are currently included in the rulemaking for OTC skin protectant drug products: allantoin, aluminum hydroxide, calamine, glycerin, petrolatum, shark liver oil, white petrolatum, and zinc oxide. The agency has reviewed the submissions to the Miscellaneous External Panel and determined that 15 submissions (Ref. 1) relate to products containing these ingredients with labeling claims for use in the treatment of diaper rash. Several submissions (Ref. 2) were for products containing lanolin, which was classified as an inactive ingredient by the Topical Analgesic Panel in its report on OTC skin protectant drug products (43 FR 34629). Three submissions included products containing vitamins A and D (Ref. 3), and two submissions included products containing mineral oil (Ref. 4). None of these ingredients was

individually classified by either Panel for use in diaper rash.

Several submissions (Ref. 5) were for products containing stabilized aloe vera for topical use for numerous indications including diaper rash, and one submission (Ref. 6) was for a product containing vitamin E for numerous skin conditions, including diaper rash. Subsequently, the manufacturers withdrew all of these submissions (Refs. 7, 8, and 9). Accordingly, the agency is not evaluating stabilized aloe vera and vitamin E in this rulemaking.

References

(1) OTC Volumes 160021, 160025, 160027, 160036, 160041, 160053, 160077, 160091, 160150, 160179, 160221, 160235, 160243, 160245, and 160357.

(2) OTC Volumes 160021, 160025, 160027, and 160179.

(3) OTC Volumes 160028, 160041, 160067, and 160179.

(4) OTC Volumes 160052 and 160086.

(5) OTC Volumes 160252, 160273, 160274, 160422, and 160423.

(6) OTC Volume 160067.

(7) Letter from B.C. Coats, Aloe Vera of America, Inc., to W. E. Gilbertson, FDA, dated April 5, 1983, in OTC Volume 06DRSTFM, Docket No. 78N-021D, Dockets Management Branch.

(8) Letter from A.J. Davis, Aloe Vera of America, Inc., to W. E. Gilbertson, FDA, dated October 24, 1986, in OTC Volume 06DRSTFM, Docket No. 78N-021D, Dockets Management Branch.

(9) Letter from S. Most, Block Drug Co., Inc., to Division of OTC Drug Evaluation, FDA, dated November 6, 1986, in OTC Volume 06DRSTFM, Docket No. 78N-021D, Dockets Management Branch.

III. The Agency's Tentative Conclusions and Adoption of the Panel's Statement

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. Summary of Ingredient Categories

Although the Panel discussed the use of skin protectant ingredients for the treatment of diaper rash, it did not review or classify any individual ingredients. All ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notices were simply listed in the Panel's statement on OTC drug products for the treatment of diaper rash (47 FR 39436 at 39439). The Panel recommended that the use of skin protectant ingredients included in this list be referred to the rulemaking for OTC skin protectant drug products and requested comments from any interested person on the use of any of these ingredients for the treatment of diaper rash.

The agency has reviewed all claimed active ingredients submitted to the Miscellaneous External Panel, the recommendations of the Topical Analgesic Panel on OTC skin protectant drug products (43 FR 34628), the tentative final monograph on OTC skin protectant drug products (48 FR 6820), and other data and information available at this time. Based upon this information, the agency is proposing the following categorization of skin protectant active ingredients for the treatment and prevention of diaper rash:

Ingredient	Category
Aldioxa	III
Allantoin	I
Aloe vera [1]	N/A
Aluminum acetate	III
Aluminum hydroxide	III
Bismuth subnitrate	II
Boric acid	II
Calamine	I
Casein (calcium casinate) [1]	N/A
Cellulose, microporous	III
Cholecalciferol	III
Cocoa butter	III
Cod liver oil (in combination)	I
Colloidal oatmeal	III
Cysteine hydrochloride	III
Dexpanthenol	III
Dimethicone	I
Glycerin	III
Kaolin	I
Lanolin (in combination)	I
Live yeast cell derivative	III
Mineral oil	I
Peruvian balsam	III
Peruvian balsam oil	III
Petrolatum	I
Protein hydrolysate (1-leucine, 1-isoleucine, 1-methionine, 1-phenylalanine, and 1-tyrosine).	III
Racemethionine	III
Shark liver oil	III
Sodium bicarbonate	III
Sulfur	II
Talc	I
Tannic acid	II
Topical starch	I
Vitamin A	III
Vitamin E [1]	N/A
White petrolatum	I
Zinc acetate	III
Zinc carbonate	III
Zinc oxide	I

[1] Not classified—withdrawn from review.

2. Testing of Category II and Category III Conditions

The agency is not proposing specific testing guidelines in this document. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any skin protectant ingredient or condition included in the review by following the procedures outlined in the agency's policy statement published in the Federal Register of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of Agency's Changes

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the substance of the Panel's statement. In the absence of a specific monograph recommendation from the Panel, the agency has developed a monograph based on its evaluations of the data and its responses to the comments above and below.

The agency has revised the Panel's definition of diaper rash, which was as follows:

> Diaper rash is a common skin problem of infancy, caused by contact with urine and feces, worsened by occlusion with plastic pants, and often secondarily infected with *Candida albicans*. (See 47 FR 39440.)

One comment noted that diaper rash is perhaps best viewed as a group of disorders rather than a specific diagnosis. The comment stated that the condition commonly referred to as diaper rash is an acute, inflammatory reaction of the skin in the diaper area, which may range from mild (characterized by mild erythema with or without chafing) to severe (characterized by vesicles, pustules, or bullae). The comment added that mild diaper rash is primarily caused by one or more diverse chemical and mechanical irritants. The comment stated that a major cause of diaper rash is the exposure of tender skin for relatively long periods of time to moisture from urine and to feces, with this exposure taking place in an enclosed, humid area. The skin is hydrated and susceptible to frictional irritation as well as chemical irritation.

In reviewing numerous articles on diaper rash that have appeared in the literature (Refs. 1 through 12), the agency notes that various authors have defined diaper rash in different ways. The agency has evaluated these, the Panel's, and the comment's definitions and is proposing the following definition in § 347.3 of this tentative final monograph:

Diaper rash or diaper dermatitis. An inflammatory skin condition in the diaper area (perineum, buttocks, lower abdomen, and inner thighs) caused by one or more of the following factors: moisture, occlusion, chafing, continued contact with urine or feces or both, or mechanical or chemical irritation. Mild conditions appear as simple erythema. More severe conditions include papules, vesicles, oozing, and ulceration.

References

(1) Arndt, K., "Diaper Rash" in "Manual of Dermatologic Therapeutics—With Essentials of Diagnosis," 2d Ed., Little, Brown and Co., Boston, p. 66–69, 1978.

(2) Brown, M.S., "Over-the-Counter Drugs for Skin Disorders—Part 3: Aids for Heat and Diaper Rash," Nurse Practioner, July/August: 28–29, 1977.

(3) Gossel, T.A., "Diaper Dermatitis," U. S. Pharmacist, 9:34–40, 1984.

(4) Honig, P.J., "Diaper Dermatitis," Postgraduate Medicine, 74:79–88, 1983.

(5) Leyden, J.J., "Diaper Dermatitis," Dermatologic Clinics, 4:23–28, 1986.

(6) Sadik, F., "OTC Products for Diaper Rash and Prickly Heat," Journal of the American Pharmaceutical Association, 1:19–24, 1970.

(7) Schanzer, M.C., and J.K. Wilkin, "Diaper Dermatitis," American Family Physician. 25:127–132, 1982.

(8) Smith, G.H., "Chapter 32—Diaper Rash and Prickly Heat Products," In "Handbook of Nonprescription Drugs," 8th Ed., American Pharmaceutical Association, Washington, pp. 643–653, 1986.

(9) Weinberg, S., and R.A. Hoekelman, "Pediatric Dermatology for the Primary Care Practitioner," McGraw-Hill, New York, p. 121, 1979.

(10) Weston, W.L., "Practical Pediatric Dermatology," Little, Brown and Co., Boston, pp. 51–53, 1979.

(11) Williams, M.L.K., "How I Treat Diaper Rashes," Medical Times, 108:50–53, 1980.

(12) Zimmerman, D.R., "Diaper-Rash Medications," in "The Essential Guide to Nonprescription Drugs," Harper and Row, New York, p. 228–237, 1983.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC skin protectant drug products for the treatment or prevention of diaper rash, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC skin protectant drug products for the treatment or prevention of diaper rash is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC skin protectant drug products for the treatment or prevention of diaper rash. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC skin protectant drug products for the treatment or prevention of diaper rash should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on skin protectant drug products for the treatment or prevention of diaper rash, a period of 180 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC skin protectant drug products used for the treatment of diaper rash. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by December 17, 1990. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before December 17, 1990, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed rulemaking. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before December 17, 1990. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register.**

Interested persons, on or before June 20, 1991, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before August 20, 1991. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA–305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph for OTC skin protectant drug products, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on August 20, 1990. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph for OTC skin protectant drug products is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 347

Labeling, Over-the-counter drugs, Skin protectants.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that subchapter D of chapter I of title 21 of the Code of Federal Regulations be amended in part 347 as

proposed in the Federal Register of February 15, 1983, 48 FR 6820; and further amended by the Federal Register of April 3, 1989, 54 FR 13490; the Federal Register of October 3, 1989, 54 FR 40808; and the Federal Register of January 31, 1990, 55 FR 3362 as follows:

PART 347—SKIN PROTECTANT DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. The authority citation for 21 CFR part 347 is revised to read as follows:

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

2. In subpart A, § 347.3(e) is added to read as follows:

§ 347.3 Definitions.

* * * * *

(e) *Diaper rash or diaper dermatitis.* An inflammatory skin condition in the diaper area (perineum, buttocks, lower abdomen, and inner thighs) caused by one or more of the following factors: moisture, occlusion, chafing, continued contact with urine or feces or both, or mechanical or chemical irritation. Mild conditions appear as simple erythema. More severe conditions include papules, vesicles, oozing, and ulceration.

3. In subpart B, § 347.10 (n), (o), (p), (q), (r), and (s) are added to read as follows:

§ 347.10 Skin protectant active ingredients.

* * * * *

(n) Cod liver oil, 5 to 13.56 percent in accordance with § 347.20(e) and provided the product is labeled so that the amount of the product that is used in a 24-hour period represents a quantity that does not exceed 10,000 U.S.P. units of vitamin A and 400 U.S.P. units of cholecalciferol.

(o) Lanolin, 15.5 percent in accordance with § 347.20(e).

(p) Mineral oil, 50 to 100 percent.

(q) Talc, 45 to 100 percent.

(r) Topical starch, 10 to 98 percent.

(s) Zinc oxide, above 25 to 40 percent in an ointment dosage form.

4. In subpart B, § 347.20(e) is added to read as follows:

§ 347.20 Permitted combinations of active ingredients.

* * * * *

(e) Any two or more of the ingredients identified in § 347.10 (a), (c), (e), (g), (h), (j), (m), (n), (o), (p), (q), (r), and (s) may be combined provided the combination is labeled according to § 347.50(b)(5) and provided each ingredient in the combination is within the concentrations specified in § 347.10.

5. In subpart C, § 347.50 is amended by revising the introductory text of paragraph (b), by adding paragraphs (b)(5) and (c)(10), by revising paragraph (d) introductory text and paragraph (d)(1), and by adding paragraph (d)(4) to read as follows:

§ 347.50 Labeling of skin protectant drug products.

* * * * *

(b) *Indications.* The labeling of the product states under the heading "Indications" one or more of the phrases listed in this paragraph (b) of this section, as appropriate. Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the act relating to misbranding and the prohibition in section 301(d) of the Federal Food, Drug, and Cosmetic Act (the act) against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

* * * * *

(5) *For products containing any ingredient in § 347.10 (a), (c), (e), (g), (h), (j), (m), (n), (o), (p), (q), (r), and (s).* "Helps treat and prevent diaper rash. Protects" (select one of the following: "chafed skin" or "minor skin irritation") (select one of the following: "due to" or "associated with") "diaper rash and helps" (select one of the following: "protect from" or "seal out") "wetness."

(c) * * *

(10) *For powder products containing kaolin identified in § 347.10(g), topical starch identified in § 347.10(r), or talc identified in § 347.10(q).* "Do not use on broken skin. Keep powder away from child's face to avoid inhalation, which can cause breathing problems."

(d) *Directions.* The labeling of the product contains the following statements, as appropriate, under the heading "Directions:"

(1) *For products labeled according to § 347.50(b) (1), (2), or (3).* "Apply liberally as often as necessary."

* * * * *

(4) *For products labeled according to § 347.50(b)(4)—(i) For all products.* "Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry. Apply" (select one of the following: "ointment," "cream," "powder," or "product") "liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged."

(ii) *For powder products only.* "Apply powder close to the body away from child's face. Carefully shake the powder into the diaper or into the hand and apply to diaper area."

* * * * *

Dated: April 24, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

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Wednesday
June 20, 1990

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 348

External Analgesic Drug Products for Over-the-Counter Human Use; Proposed Rule for Diaper Rash Drug Products

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 348

[Docket No. 78N-301D]

RIN 0905-AA06

External Analgesic Drug Products for Over-the-Counter Human Use; Proposed Rulemaking for Diaper Rash Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking amending the notice of proposed rulemaking for over-the-counter (OTC) external analgesic drug products. (See the **Federal Register** of February 8, 1983; 48 FR 5852.) This part of the proposed rulemaking concerns conditions under which OTC external analgesic drug products for the treatment or prevention of diaper rash are not generally recognized as safe and effective, and are misbranded. FDA is issuing this notice of proposed rulemaking after considering the statement on OTC drug products for the treatment of diaper rash of the Advisory Review Panel on OTC Miscellaneous External Drug Products and public comments on an advance notice of proposed rulemaking that was based on that statement. The agency's proposals concerning the use of other OTC diaper rash drug products are being published elsewhere in this issue of the **Federal Register**. These proposals are part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed rulemaking before the Commissioner of Food and Drugs by December 17, 1990. The agency is allowing a period of 180 days for comments and objections instead of the normal 60 days for the following reasons: (1) The concurrent publication of four rulemakings regarding OTC diaper rash drug products and (2) this document contains the agency's initial evaluation of the submissions of data on OTC diaper rash drug products that were made to, but not reviewed by, the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel). New data by June 20, 1991. Comments on the new data by August 20, 1991. Written comments on the agency's economic impact determination by December 17, 1990.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-6000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 7, 1982, FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), advance notices of proposed rulemaking and reopened the administrative records for OTC topical antifungal drug products (47 FR 39464), topical antimicrobial drug products (47 FR 39406), external analgesic drug products (47 FR 39412), and skin protectant drug products (47 FR 39436) to allow for consideration of a statement on OTC drug products for the treatment of diaper rash prepared by the Miscellaneous External Panel, which was the advisory review panel responsible for evaluating data on the active ingredients used for the treatment of diaper rash. Interested persons were invited to submit comments by December 6, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by January 5, 1983.

In the **Federal Register** of December 28, 1982 (47 FR 57738), in response to a request for an extension of time, the comment period and reply comment period for OTC external analgesic drug products were extended to February 4, 1983, and to March 7, 1983, respectively.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

Seven drug manufacturers, one trade association, and one manufacturer of diapers submitted comments. Most of these comments are general in scope and were submitted to more than one of the four rulemakings mentioned above except one comment which was submitted to the external analgesic rulemaking only. All of the overlapping comments were submitted to the rulemaking for OTC skin protectant drug products. In those cases where the same comments were submitted to more than one rulemaking, the comments are being addressed only once—in the notice of proposed rulemaking to amend the notice of proposed rulemaking for OTC skin protectant drug products. Copies of the comments received are on public display in the Dockets Management Branch.

The Panel provided a general statement on OTC drug products for the treatment of diaper rash, but did not review individual ingredients nor develop labeling for diaper rash drug products. The agency is aware that a number of diaper rash drug products are labeled for both the treatment and prevention of diaper rash. Therefore, the agency is expanding the scope of this rulemaking to include drug products labeled for both or either use.

In this notice of proposed rulemaking, FDA responds to public comment and states for the first time its position on OTC external analgesic drug products for the treatment or prevention of diaper rash. Final agency action on this matter will occur with the publication at a future date of a final rule relating to OTC external analgesic drug products for use in diaper rash. Other documents concerning the use of OTC topical antifungal drug products, OTC topical antimicrobial drug products, and OTC skin protectant drug products for the treatment or prevention of diaper rash are being published separately, elsewhere in this issue of the **Federal Register**. This proposal constitutes FDA's tentative adoption of the Panel's statement on OTC external analgesic drug products for use in diaper rash as modified on the basis of the comments received and the agency's independent evaluation of the Panel's statement.

The OTC procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug

products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the Federal Register of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the advance notice of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

The agency has reviewed the comments submitted to this rulemaking and, as noted above, determined that most of the comments were submitted to more than one of the four rulemakings related to OTC diaper rash drug products. The majority of the comments are general in scope or deal primarily with the use of skin protectant active ingredients. The agency has decided to address all of these general comments in a single rulemaking, which is the notice of proposed rulemaking to amend the tentative final monograph for OTC skin protectant drug products, published elsewhere in this issue of the Federal Register.

Regarding those portions of the comments that concerned external analgesic active ingredients, one comment stated that it had submitted information on the safety and efficacy of baking soda (sodium bicarbonate) used as an external analgesic and as a skin protectant. Referring to FDA's decision, published in the tentative final monograph for OTC skin protectant drug products (February 15, 1983; 48 FR 6820 at 6830), that transferred sodium bicarbonate from the rulemaking for OTC skin protectant drug products to the rulemaking for OTC external analgesic drug products, the comment stated that baking soda should be considered in both rulemaking.

At the time that the tentative final monograph for OTC skin protectant drug products was published, the agency had determined that, based on the claims for sodium bicarbonate the Panel had discussed in that rulemaking (e.g., for the temporary relief of pain and itching due to minor burns, sunburn, * * * insect bites, and minor skin irritations), those uses for sodium bicarbonate would more appropriately be addressed in the rulemaking for OTC external analgesic drug products. Now that the agency has reviewed the information on the use of sodium bicarbonate for the treatment and prevention of diaper rash, as discussed elsewhere in this issue of the Federal Register, the agency has determined that the diaper rash uses of sodium bicarbonate should be included in the skin protectant rulemaking. Accordingly, as the comment requested, sodium bicarbonate is now being considered in both rulemakings.

Another comment, in discussing the Panel's referral of diaper rash ingredients to the various rulemakings, noted that some of the ingredients which are not skin protectants are classified as irritants that may indeed be found harmful when used in the diaper area. The comment added that this would be especially true of many of the referred external analgesic ingredients. This is discussed in Part III. below—The Agency's Tentative Conclusions and Adoption of the Panel's Statement.

Another comment, submitted only to the external analgesic rulemaking, suggested that the indications in the tentative final monograph in proposed § 348.50(b)(4) (48 FR 5852 at 5868) be revised in order to state more clearly the uses for which aluminum acetate solution is recommended. Part of the proposed revision would read: "a soothing wet dressing for relief of skin irritations" caused by various conditions including diaper rash. The agency believes that "relief of skin irritations" is basically a skin protectant claim, therefore, this comment is more appropriately addressed in the rulemaking for OTC skin protectant drug products for diaper rash. (See discussion of aluminum acetate used as a skin protectant, published elsewhere in this issue of the Federal Register.)

One additional comment, regarding several products containing colloidal oatmeal as the principal active ingredient, was submitted in response to the publication of the tentative final monograph for OTC external analgesic drug products (February 8, 1983; 48 FR 5852). The comment submitted data and requested that FDA include colloidal oatmeal in the monograph for OTC external analgesic drug products as an ingredient generally recognized as safe and effective for the following indications: "For prompt temporary relief of itchy, sore, sensitive skin due to rashes, eczema/psoriasis, hemorrhoidal and genital irritations, diaper rash, chicken pox, prickly heat, hives, poison ivy/oak, and sunburn."

In this document, the agency is addressing only one aspect of the comment's request: The antipruritic (anti-itch) use of colloidal oatmeal as it pertains to diaper rash. The agency will address the antipruritic use of colloidal oatmeal for the other conditions stated above in a future Federal Register publication pertaining to the rulemaking for OTC external analgesic drug products. The agency discussed the skin protectant use of colloidal oatmeal for providing skin protection and relieving minor irritation and itching due to poison ivy, poison oak, poison sumac, and insect bites in the notice of proposed rulemaking amending the tentative final monograph for OTC skin protectant drug products. (See 54 FR 40808 at 40809 to 40811; October 3, 1989.)

As stated in Part III. below—The Agency's Tentative Conclusions and Adoption of the Panel's Statement, the agency has determined that external analgesic active ingredients should not be included in OTC diaper rash drug products because infants and young children (the target population for these products) would not be able to communicate verbally their symptoms to a parent and, thus, the need for an anti-itch external analgesic ingredient could not be appropriately determined. However, the fact that colloidal oatmeal cannot be used in an OTC diaper rash drug product bearing an anti-itch claim does not prevent colloidal oatmeal from being used in an OTC diaper rash drug product bearing only skin protectant

claims. (See the discussion of colloidal oatmeal used as a skin protectant in the notice of proposed rulemaking to amend the tentative final monograph for OTC skin protectant drug products published elsewhere in this issue of the **Federal Register.**)

II. The Agency's Evaluation of the Submissions

Of the ingredients listed in the Panel's statement on OTC drug products for diaper rash, the following are currently included in the rulemaking for OTC external analgesic drug products: Benzocaine, camphor, dibucaine, eucalyptol, hydrocortisone acetate, menthol, oil of cade, oil of eucalyptus, phenol, pramoxine, resorcinol, and tetracaine (47 FR 39415 and 39416). The agency has reviewed the submissions to the Panel and determined that only three submissions were for products that contained one or more of the above ingredients with labeling claims for use in the treatment of diaper rash (Refs. 1, 2, and 3).

One submission was for a combination product containing the ingredients methylbenzethonium chloride, zinc oxide, calamine, and eucalyptol. These ingredients were identified in the labeling submitted (Ref. 1), and the product was promoted as a "diaper rash ointment." However, the active ingredient section of the submission did not identify eucalyptol as an active ingredient, and the submission did not contain any safety or efficacy data on the use of eucalyptol as an external analgesic active ingredient to prevent or treat diaper rash. The ingredient methylbenzethonium chloride is discussed in the proposed rulemaking for OTC antimicrobial diaper rash drug products, and the ingredients calamine and zinc oxide are discussed in the proposed rulemaking for OTC skin protectant diaper rash drug products, published elsewhere in this issue of the **Federal Register.**

The second submission was for a combination product for which the manufacturer claimed nine active ingredients, two of which were juniper tar (oil of cade) and resorcinol (Ref. 2). However, the submission did not contain any specific information on the safety and efficacy of juniper tar and resorcinol as external analgesic active ingredients for use in diaper rash. Based on the product's current labeling (Ref. 3), the product has been reformulated and no longer contains juniper tar.

The third submission was for a combination product containing two percent dexpanthenol, 0.1 percent menthol, and 0.1 percent camphor labeled for "relief of itching and discomfort in minor skin disorders" and "useful in diaper rash" (Ref. 4). Effectiveness data pertaining to diaper dermatitis consisted of two reports of clinical experience using a cream containing dexpanthenol to treat diaper dermatitis (Refs. 5 and 6). In one report, it was noted that the combination product reduced inflammation within 24 hours after initiation of treatment, i.e., application of the product to the affected areas each time the diaper was changed (Ref. 5). In the second report, based on 12 years of clinical experience using a cream containing pantothenylol, it was noted that 23 out of 28 cases of diaper dermatitis were treated with satisfactory results, while 5 of the 28 cases resulted in unsatisfactory results (Ref. 6). [Pantothenylol is now known as dexpanthenol (Ref. 7).] In both reports, the amount of data presented is very limited. Further, both reports make reference to use of a combination product. Neither report provides any evidence to establish that the menthol or camphor component contributed to the results observed.

The agency concludes that the submissions made to the Panel are inadequate to establish the safety and effectiveness of any OTC external analgesic active ingredient for the treatment or prevention of diaper rash.

References

(1) OTC Volume 160027.

(2) OTC Volume 160040.

(3) Letter from J.A. Devaney, The Mentholatum Co., Inc., to L. Geismar, FDA, October 23, 1986, OTC Volume 06DRETFM, Docket No. 78N-301D, Dockets Management Branch.

(4) OTC Volumes 160104 and 160204.

(5) Dubow, E. "Ammoniacal Napkin Dermatitis in Infants," *Archives of Pediatrics*, 71:323–326, 1954.

(6) Kline, P.R., "12 Years Experience Using Panthothenylol Topically," *Western Medicine*, 4:78, 1963.

(7) Budavari, S., editor," "The Merck Index," 11th Ed., Merck & Co., Inc., Rahway, NJ, 1989, s.v. "dexpanthenol."

III. The Agency's Tentative Conclusions and Adoption of the Panel's Statement

Although the Panel discussed the use of external analgesic ingredients for the treatment of diaper rash, it did not review or classify any individual ingredients. All ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notice were simply listed in the Panel's statement on OTC drug products for the treatment of diaper rash (47 FR 39412 at 39415). The Panel recommended that the use of external analgesic ingredients included in this list be referred to the rulemaking for OTC external analgesic drug products and requested comments from any interested person on the use of any of these ingredients for the treatment of diaper rash.

As discussed above, only three of the comments addressed the use of external analgesic active ingredients in diaper rash drug products. The agency has determined that the use of these ingredients—sodium bicarbonate, aluminum acetate, and colloidal oatmeal—for the treatment or prevention of diaper rash is more appropriately addressed in the rulemaking for OTC skin protectant drug products.

The other data submitted have been inadequate to support the use of any other external analgesic active ingredients in the treatment or prevention of diaper rash.

In the tentative final monograph for OTC external analgesic drug products, the agency stated that external analgesic active ingredients are intended for the relief of pain and/or itching, or for the relief of minor aches and pains (48 FR 5852 at 5868). The agency also stated that these ingredients should not be used on children under 2 years of age except as recommended by a physician in order to provide an adequate margin of safety (48 FR 5869). The agency discussed the possibility of cutaneous absorption due to occlusion of the skin, as from a diaper or from lying on a waterproof mattress or from body folds touching each other, and mentioned that analgesic drugs can also be corrosive to infants' skin under occlusion (48 FR 5864). The agency added that children at the age of 2 years are just beginning to learn to communicate verbally in expressing their symptoms to a parent, whereas children below the age of 2 years are more passive and less able to express and localize symptoms [to a parent]. In addition, as one comment noted, many external analgesic active ingredients are classified as irritants that may be harmful when used in the diaper area. For these reasons, the agency does not believe that external analgesic active ingredients should be present in OTC diaper rash drug products. In addition, there is a lack of data to show that any OTC external analgesic active ingredients are generally recognized as safe and effective for the treatment or prevention of diaper rash. The agency therefore is proposing that OTC drug products labeled for the treatment and/or prevention of diaper rash be formulated to contain no external analgesic ingredients.

Accordingly, based on all information available to date, the agency is

proposing that any OTC external analgesic drug product labeled for the treatment and/or prevention of diaper rash is not generally recognized as safe and effective. If this proposal is ultimately adopted, upon the effective date of that portion of the final rule for OTC external analgesic drug products that applies to OTC diaper rash drug products, any OTC drugs containing external analgesic active ingredients and labeled for the treatment and/or prevention of diaper rash that are initially introduced or initially delivered for introduction into interstate commerce would be regarded as unapproved new drugs and subject to regulatory action. Manufacturers are encouraged to comply voluntarily with the proposed rule at the earliest possible date.

The agency emphasizes that the final rule for OTC external analgesic drug products, as it relates to OTC diaper rash drug products, will not apply to (1) active ingredients included in the external analgesic final monograph that are Category I antipruritics for claims other than diaper rash and (2) active ingredients included in both the external analgesic and skin protectant rulemakings where the ingredient is a Category I skin protectant making allowable diaper rash skin protectant claims, e.g., sodium bicarbonate.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC external analgesic drug products for the treatment or prevention of diaper rash, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC external analgesic drug products for the treatment or prevention of diaper rash is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC external analgesic drug products for the treatment or prevention of diaper rash. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC external analgesic drug products for the treatment or prevention of diaper rash should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on external analgesic drug products for the treatment or prevention of diaper rash, a period of 180 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC external analgesic drug products used for the treatment of diaper rash. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by December 17, 1990. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c) (6) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before December 17, 1990, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed rulemaking. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before December 17, 1990. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register.**

Interested persons, on or before June 20, 1991, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before August 20, 1991. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA–305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph for OTC external analgesic drug products, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on August 20, 1991. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph for OTC external analgesic drug products is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

Dated: April 24, 1990.

James S. Benson,*

Acting Commissioner of Food and Drugs.

[FR Doc. 90–13652 Filed 6–19–90; 8:45 am]

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federal register

Wednesday
June 20, 1990

Part IV

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 333

Topical Antifungal Drug Products for Over-the-Counter Human Use; Proposed Rule for Diaper Rash Drug Products

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR Part 333

[Docket No. 80N-476D]

RIN 0905-AA06

Topical Antifungal Drug Products for Over-the-Counter Human Use; Proposed Rulemaking for Diaper Rash Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking amending the notice of proposed rulemaking for over-the-counter (OTC) topical antifungal drug products. (See the **Federal Register** of December 12, 1989; 54 FR 51136). This part of the proposed rulemaking concerns conditions under which OTC topical antifungal drug products for the treatment or prevention of diaper rash are not generally recognized as safe and effective, and are misbranded. FDA is issuing this notice of proposed rulemaking after considering the statement on OTC drug products for the treatment of diaper rash of the Advisory Review Panel on OTC Miscellaneous External Drug Products and public comments on an advance notice of proposed rulemaking that was based on that statement. The agency's proposals concerning the use of other OTC diaper rash drug products are being published elsewhere in this issue of the **Federal Register**. These proposals are part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed rulemaking before the Commissioner of Food and Drugs by December 17, 1990. The agency is allowing a period of 180 days for comments and objections instead of the normal 60 days for the following reasons: (1) The concurrent publication of four rulemakings regarding OTC diaper rash drug products and (2) this document contains the agency's initial evaluation of the submissions of data on OTC diaper rash drug products that were made to, but not reviewed by, the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel). New data by June 20, 1991. Comments on the new data by August 20, 1991. Written comments on the agency's economic impact determination by December 17, 1990.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 7, 1982, FDA published, under § 330.10(a)(6) (21 CFR 330.10(a)(6)), advance notices of proposed rulemaking and reopened the administrative records for OTC topical antifungal drug products (47 FR 39464), topical antimicrobial drug products (47 FR 39406), external analgesic drug products (47 FR 39412), and skin protectant drug products (47 FR 39436) to allow for consideration of a statement on OTC drug products for the treatment of diaper rash prepared by the Miscellaneous External Panel, which was the advisory review panel responsible for evaluating data on the active ingredients used for the treatment of diaper rash. Interested persons were invited to submit comments by December 6, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by January 5, 1983.

In the **Federal Register** of December 28, 1982 (47 FR 57738), in response to a request for an extension of time, the comment period and reply comment period for OTC topical antifungal drug products were extended to February 4, 1983, and to March 7, 1983, respectively.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

Two drug manufacturers, one trade association, and one manufacturer of diapers submitted comments. Most of these comments are general in scope and were submitted to more than one of the four rulemakings mentioned above. All of the overlapping comments were submitted to the rulemaking for OTC skin protectant drug products. In those cases where the same comments were submitted to more than one rulemaking, the comments are being addressed only once—in the notice of proposed rulemaking to amend the notice of proposed rulemaking for OTC skin protectant drug products. Copies of the comments received are on public display in the Dockets Management Branch.

The Panel provided a general statement on OTC drug products for the treatment of diaper rash, but did not review individual ingredients nor develop labeling for diaper rash drug products. The agency is aware that a number of diaper rash drug products are labeled for both the treatment and prevention of diaper rash. Therefore, the agency is expanding the scope of this rulemaking to include drug products labeled for both or either use.

In this notice of proposed rulemaking, FDA responds to public comment and states for the first time its position on OTC topical antifungal drug products for the treatment or prevention of diaper rash. Final agency action on this matter will occur with the publication at a future date of a final rule relating to OTC topical antifungal drug products for use in diaper rash. Other documents concerning the use of OTC topical antimicrobial drug products, OTC external analgesic drug products, and OTC skin protectant drug products for the treatment or prevention of diaper rash are being published separately, elsewhere in this issue of the **Federal Register**. This proposal constitutes FDA's tentative adoption of the Panel's statement on OTC topical antifungal drug products for use in diaper rash as modified on the basis of the comments received and the agency's independent evaluation of the Panel's statement.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally

recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. Similarly, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the Federal Register of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the advance notices of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

The agency has reviewed the comments submitted to this rulemaking and, as noted above, determined that most of the comments were submitted to more than one of the four rulemakings related to OTC diaper rash drug products. The majority of the comments are general in scope or deal primarily with the use of skin protectant active ingredients. The agency has decided to address all of these general comments in a single rulemaking, which is the notice of proposed rulemaking to amend the tentative final monograph for OTC skin protectant drug products, published elsewhere in this issue of the Federal Register. These comments are incorporated into this rulemaking.

Regarding those portions of the comments that concerned topical antifungal active ingredients, one comment stated that secondary infections caused by bacteria and fungus may accompany diaper rash as complications; however, unlike common diaper rash, such secondary infections should be diagnosed and treated by a physician.

The agency agrees with the comment that complications of common diaper rash should be diagnosed and treated by a physician. Fungal and bacterial infections are the most common complications of diaper rash and usually result from a lack of treatment or improper treatment of the initial condition. The moist, warm, alkaline environment created by unchanged diapers is conducive to the proliferation of many bacteria and fungi which, in this environment, can cause secondary infections. Because the clinical picture is often obscure, the only precise method of determining the cause of the secondary infection is by laboratory analysis of scrapings from the affected area (Ref. 1). Therefore, a physician should be consulted for a definitive diagnosis followed by appropriate treatment of complications of diaper rash.

As stated in Part III. below—The Agency's Tentative Conclusions and Adoption of the Panel's Statement, the agency has determined that topical antifungal active ingredients should not be included in OTC diaper rash drug products because a fungus infection associated with diaper rash in infants and young children (the target population for these products) would not be amenable to proper diagnosis and treatment without the aid of a physician.

Reference

(1) Smith, G.H., "Diaper Rash and Prickly Heat Products," *in* "Handbook of Nonprescription Drugs," 8th Ed., American Pharmaceutical Association, Washington, p. 644, 1986.

II. The Agency's Evaluation of the Submissions

Of the ingredients listed in the Panel's statement, the following are currently included in the rulemaking for OTC topical antifungal drug products: benzethonium chloride, boric acid, calcium undecylenate, camphor, chloroxylenol, 8-hydroxyquinoline, menthol, phenol, resorcinol, and salicylic acid. The agency has reviewed the submissions to the Panel and determined that only one submission was for a product containing any of these ingredients with labeling claims for antifungal activity for use in the treatment of diaper rash (Ref. 1). Another submission (Ref. 2) was for a diaper rash product with antifungal claims containing the ingredient sodium propionate, which was not listed in the Panel's statement, but was included in the rulemaking for OTC topical antifungal drug products.

The first submission was for two products (an ointment and a powder) for which the manufacturer's labeling listed the antifungal, calcium undecylenate, as the active ingredient (Ref. 1). Other information in the submission indicated that boric acid was also an active ingredient in the powder product. Both products were promoted for diaper rash, prickly heat, chafing, and minor skin irritations. Calcium undecylenate is discussed for its antifungal claims in this proposal and for its antibacterial claims in the proposal for OTC topical antimicrobial diaper rash drug products published elsewhere in this issue of the Federal Register.

The submission on the products containing 15 percent calcium undecylenate (ointment) and 15 percent calcium undecylenate and 3 percent boric acid (powder) did not include any studies on the ointment. Summaries of clinical studies and related case histories described the use of a powder product containing 5-percent boric acid and 15 percent calcium undecylenate on infants with diaper dermatitis and reported that successful therapeutic results were obtained in most cases. One large-scale clinical investigation (Ref. 3) reported a 12.5-percent incidence of rashes in 168 babies who had clear skin at the start of the study and who were treated with a powder containing 5 percent boric acid and 15 percent calcium undecylenate compared to a 21 percent incidence of rashes in 114 babies who were treated with a powder containing 5 percent boric acid but no calcium undecylenate. No evidence of skin irritation attributable to the boric acid/calcium undecylenate powder was observed in studies where infants received the powder as treatment for diaper rash or when it was used prophylactically. However, none of these studies provide sufficient data on the use of a lower concentration of calcium undecylenate alone to establish the safety and efficacy of the ingredient.

Since the time of the original submission, both products have been reformulated (Ref. 4). The powder product now contains 10 percent calcium undecylenate as the sole active ingredient, and the ointment product contains 53.9 percent petrolatum and 15 percent zinc oxide as the active ingredients.

Additional studies, both published and unpublished, have been submitted (Ref. 4) to demonstrate the antibacterial and antifungal activity of undecylenic acid and its salts for use on diaper rash. In in vitro studies using 5, 10, and 15 percent calcium undecylenate, significant zones of inhibition of *Candida albicans* (*C. albicans*) were demonstrated. One additional in vivo study involving 200 infants with varying degrees of diaper rash was submitted. One hundred of the infants were treated with a 15-percent calcium undecylenate/3-percent boric acid product and the remaining infants were treated with cornstarch or a bland baby powder and served as the control group. Cultures were taken and examined from all the infants. Of the six cases with *C. albicans* treated with the powder product, improvement was reportedly excellent in two cases and moderate in four cases. No data were provided on the control group. The agency concludes that the submitted studies are not adequately controlled and involve such a variety of concentrations of the undecylenate active ingredient, often with the active ingredient boric acid as well, that the effectiveness of 10 percent calcium undecylenate as the sole active ingredient has not been demonstrated and that additional studies are needed. There also remains a safety concern regarding use of any antifungal ingredient on infants. Undecylenic acid and its salts were recommended as Category I ingredients for use in the treatment of athlete's foot, jock itch, and ringworm by the Advisory Review Panel on OTC Antimicrobial (II) Drug Products. (See the **Federal Register** of March 23, 1982; 47 FR 12480.) The Panel required the following warning for all OTC topical antifungal drug products: "Do not use on children under 2 years of age except under the advice and supervision of a doctor."

The agency concurred with the Panel's Category I classification of undecylenic acid and its salts as well as the Panel's recommended warning for these products in the tentative final monograph for OTC topical antifungal drug products published in the **Federal Register** of December 12, 1989 (54 FR 51136 at 51146).

The second submission (Ref. 2) involves a product containing 5 percent sodium propionate and 0.0125 percent water-soluble derivatives of chlorophyll, labeled as a fungistatic, emollient ointment with a number of indications for use, including diaper rash. The company provided the information that the concentration of water-soluble chlorophyllin in the product was determined on the basis of that amount which proved necessary to effectively deodorize the propionate content and thereby make the preparation acceptable to patients. The submission cites a number of studies and review articles which report the safe and effective use of this product for a variety of dermatological conditions including diaper rash. However, none of these studies is a well-controlled clinical test.

The Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products recommended calcium and sodium propionate as Category I active ingredients for the relief of minor irritations of the vagina, based on clinical data on a product that has been marketed for 30 years as a prescription item. (See 48 FR 46694 at 46704; October 13, 1983.) The Panel also recommended the professional labeling claim "For the treatment of *Candida albicans*" for the propionates. The agency dissented from both of the Panel's recommendations because the data on the prescription product were reviewed under the Drug Efficacy Study Implementation (DESI) program, and it was found that the drug lacks substantial evidence of effectiveness (48 FR 46695). Accordingly, the agency placed the professional labeling indication recommended by the Panel in Category II and is not allowing OTC marketing of calcium or sodium propionate products for vaginal use.

The Advisory Review Panel on OTC Antimicrobial (II) Drug Products reviewed propionic acid and its salts for use in the treatment of athlete's foot, jock itch, and ringworm and found that these ingredients are safe, but that there are insufficient data available to permit final classification of their effectiveness. (See 47 FR 12480 at 12541; March 23, 1982.) With regard to the Category I classification for safety, the Panel recommended that all OTC antifungal drug products bear the label warning "Do not use in children under 2 years of age except under the advice and supervision of a doctor." The agency concurred with the Panel's recommendations in the tentative final monograph for OTC antifungal drug products (54 FR 51136 at 51161).

The agency tentatively concludes that neither the safety nor effectiveness of the propionates for use on infants has been adequately demonstrated, and that additional data are needed to support Category I status for use of any of the propionates in the treatment or prevention of diaper rash.

References

(1) OTC Volume 160236.

(2) OTC Volume 160105.

(3) Vignec, A.J., "Report on Prophylactic and Therapeutic Use of Desenex Baby Powder for a Three-Month Period Ending November 1," in OTC Volume 160236, pp. 83–116.

(4) Comment No. Rpt, Docket No. 80N–0476, Dockets Management Branch.

III. The Agency's Tentative Conclusions and Adoption of the Panel's Statement

Although the Panel discussed the use of topical antifungal ingredients for the treatment of diaper rash, it did not review or classify any individual ingredients. All ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notices were simply listed in the Panel's statement on OTC topical antifungal drug products for the treatment of diaper rash (47 FR 39464). The Panel recommended that the use of topical antifungal ingredients included in this list be referred to the rulemaking for OTC topical antifungal drug products and requested comments from any interested person on the use of any of these ingredients for the treatment of diaper rash. The Panel did note that common diaper rash is often accompanied by a secondary infection of *C. albicans*, which is frequently present in feces and proliferates under the diaper to produce a characteristic bright red, sharply marginated rash with satellite pustules and erosions. The Panel also pointed out that physicians treat severe diaper rash with topical antifungal and anticandidal drugs, often in combination with a topical steroid (47 FR 39467).

As discussed above, only one of the comments addressed the use of topical antifungal active ingredients in diaper rash drug products. The agency agrees with the comment that fungus infections associated with diaper rash are not suitable for self-treatment by consumers and should be diagnosed and treated by a physician. This position is also supported by the Panel's comments about the type of treatment used when diaper rash is complicated by fungus (47 FR 39467). Other authors also agree with the Panel. For example, Schanzer and Wilkin (Ref. 2) and Honig (Ref. 3) state that only simple diaper rash should be treated with OTC drugs, and, if the rash has not healed in a reasonable amount of time, a secondary infection may be present (Refs. 1 and 2). Numerous authors point out that diaper dermatitis includes diverse disorders which appear in the diaper area, and identifying the etiology of a diaper rash and selecting the therapeutic agent are difficult even for a physician (Refs. 2 through 6). Schanzer and Wilkin (Ref. 2) noted that the diagnostic range includes irritant

dermatitis, allergic dermatitis, intertrigo, seborrheic dermatitis, atopic eczema, candidiasis, psoriasis, scabies, miliaria, bullous impetigo, and granuloma gluteale infantum. These authors developed a full page flow chart for the decisional process of diagnosing and treating diaper dermatitis to be used by family physicians before they refer a patient to a dermatologist.

The agency agrees with these experts that laypersons do not have adequate medical background or training to diagnose and treat such infections or other conditions in the diaper area. The agency believes that a physician should be consulted for diagnosis and appropriate therapy for the different types of diaper dermatitis described above, including fungal infection. In addition, as discussed below, topical antifungal drugs actually "treat" the underlying disease rather than merely alleviate symptoms. Accordingly, the agency believes it is appropriate that these drugs be used for diaper rash only under the supervision of a physician.

In the tentative final monograph for OTC topical antifungal drug products, the agency stated that topical antifungal drugs are different from most OTC drug products in that they actually treat the underlying disease rather than only ameliorate signs and symptoms (54 FR 51136 at 51154). The agency also proposed a label warning that these ingredients should not be used on children under 2 years of age except as recommended by a physician (54 FR 51161). In an adult, the surface area of contact is small (probably less than 5 percent) when antifungals are used for the approved OTC indications, i.e., athlete's foot, jock itch, and ringworm. In infants, the affected area of diaper rash may be 10 to 15 percent of the body surface. Additionally, inflamed and often open surface areas are more permeable than normal skin and permit a greater degree of absorption especially under occlusion as with a diaper. For these reasons, the agency does not believe that topical antifungal active ingredients should be used in OTC diaper rash drug products.

The presence of *C. albicans* in simple diaper rash is not clearly defined. Brookes, Hubbert, and Sarkany (Ref. 7) studied 60 infants on their regular well-baby visits to a family health clinic to determine the incidence of diaper rash and to clinically evaluate early cases. Cultures were taken from the skin of the normal group and the diaper rash group. *C. albicans* was recovered in only two of the infants with diaper rash (8 percent) and in none of the normal infants. The authors noted that *C. albicans* had a much higher incidence in other studies that included infants with long established and treated cases of diaper rash. The authors added that they had included in their study only infants in which diaper rash was an incidental finding and concluded that *C. albicans* plays no etiological role in early cases of diaper rash.

Pittillo et al. (Ref. 8) studied the microbial skin flora of the diaper area of 10 infants without a recent history of diaper dermatitis and 10 infants affected with diaper dermatitis. *C. albicans* was not recovered from the diaper area cultures of either test group.

In a study by Brown, Tyson, and Wilson (Ref. 9), six children in the control group had previously been studied while they had diaper rash; *C. albicans* was isolated from one child. This organism was not isolated following recovery.

Montes et al. (Ref. 10) obtained bacterial and fungal cultures from the diaper area of 35 infants with diaper dermatitis and from 25 normal controls. The infants with diaper rash were treated by their pediatricians by means of usual (unspecified) topical measures, and then 25 of the infants were recultured after cure of the dermatitis and while the infants were still wearing diapers. The after-cure infants were not sampled for at least 2 months to provide enough time to allow recolonization of the diaper area by the normal microbial flora. It was apparent that the presence of *C. albicans* differed in the after-cure group and the normal group compared to the diaper rash group. *C. albicans* was recovered from 77.1 percent of the infants with diaper rash, 8 percent of the after-cure infants, and 12 percent of the normal control infants. Because the treatments used on the infants were not described, it cannot be determined whether the changes in the microbial flora were due to the use of topical antimicrobial drugs or due to other conditions as the diaper rash cleared.

Based on the above studies, the agency believes that there is a lack of adequate data to determine if OTC topical antifungal active ingredients are needed for the treatment or prevention of simple diaper rash. Accordingly, based on all information available to date, the agency is proposing that any OTC topical antifungal drug product labeled for the treatment and/or prevention of diaper rash is not generally recognized as safe and effective. If this proposal is ultimately adopted, all OTC drug products labeled for the treatment and/or prevention of diaper rash would need to be formulated to contain no topical antifungal ingredients. Upon the effective date of that portion of the final rule for OTC topical antifungal drug products that applies to OTC diaper rash drug products, any OTC drug products containing topical antifungal active ingredients and labeled for the treatment and/or prevention of diaper rash that are initially introduced or initially delivered for introduction into interstate commerce would be regarded as unapproved new drugs and subject to regulatory action. Manufacturers are encouraged to comply voluntarily with the proposed rule at the earliest possible date.

References

(1) Smith, G.H., "Diaper Rash and Prickly Heat Products," *in* "Handbook of Nonprescription Drugs," 8th Ed., American Pharmaceutical Association, Washington, pp. 643–653, 1986.

(2) Schanzer, M.C., and J.K. Wilkin, "Diaper Dermatitis," *American Family Physician*, 25:127–132, 1982.

(3) Honig, P.J., "Diaper Dermatitis: Factors to Consider in Diagnosis and Treatment," *Postgraduate Medicine*, 74:79–88, 1983.

(4) Williams, M.L.K., "How I Treat Diaper Rashes," *Medical Times*, 108:50–53, 1980.

(5) Leyden, J.J., "Diaper Dermatitis," *Dermatologic Clinics*, 4:23–28, 1986.

(6) Weston, W.L., A.T. Lane, and J.A. Weston, "Diaper Dermatitis: Current Concepts," *Pediatrics*, 66:532–536, 1980.

(7) Brookes, D.B., R.M. Hubbert, and I. Sarkany, "Skin Flora of Infants with Napkin Rash," *The British Journal of Dermatology*, 85:250–253, 1971.

(8) Pittillo, R.F., et al., "Bacterial Flora of Infants' Skin: Comparison Between Diaper-Occluded and Unoccluded Areas," *International Journal of Dermatology*, 12:245–249, 1973.

(9) Brown, C.P., R.M. Tyson, and F.H. Wilson, "Dermatitis (Diaper Rash): A Bacteriologic Study of the Diaper Region," *The Pennsylvania Medical Journal*, 55:755–758, 1952.

(10) Montes, L.F., et al., "Microbial Flora of Infant's Skin: Comparison of Types of Microorganisms Between Normal Skin and Diaper Dermatitis," *Archives of Dermatology*, 103:400–406, 1971.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the **Federal Register** of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for

OTC topical antifungal drug products for the treatment or prevention of diaper rash, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC topical antifungal drug products for the treatment or prevention of diaper rash is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC topical antifungal drug products for the treatment or prevention of diaper rash. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC topical antifungal drug products for the treatment or prevention of diaper rash should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on topical antifungal drug products for the treatment or prevention of diaper rash, a period of 180 days from the date of publication of this proposed rulemaking in the **Federal Register** will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC topical antifungal drug products used for the treatment of diaper rash. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by December 17, 1990. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before December 17, 1990, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed rulemaking. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before December 17, 1990.Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 am. and 4 pm., Monday through Friday. Any scheduled oral hearing will be announced in the **Federal Register.**

Interested persons, on or before June 20, 1991, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before August 20, 1991. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the **Federal Register** of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA–305) (address above). Received data and comments may also be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph for OTC topical antifungal drug products, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on August 20, 1990. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph for OTC topical antifungal drug products is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

Dated: April 24, 1999.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90–13650 Filed 6–19–90; 8:45 am]

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Wednesday
June 20, 1990

Part V

Department of Health and Human Services

Food and Drug Administration

21 CFR Part 333

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Rule for Diaper Rash Drug Products

DEPARTMENT OF HEALTH AND HUMAN SERVICES

21 CFR PART 333

[Docket No. 75N-183D]

RIN 0905-AA06

Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Proposed Rulemaking for Diaper Rash Drug Products

AGENCY: Food and Drug Administration.

ACTION: Notice of proposed rulemaking.

SUMMARY: The Food and Drug Administration (FDA) is issuing a notice of proposed rulemaking amending the tentative final monograph (proposed rule) for over-the-counter (OTC) topical antimicrobial drug products. The proposed rulemaking would establish conditions under which OTC topical antimicrobial drug products for the treatment or prevention of diaper rash are generally recognized as safe and effective and not misbranded. FDA is issuing this notice of proposed rulemaking after considering the statement on OTC drug products for the treatment of diaper rash of the Advisory Review Panel on OTC Miscellaneous External Drug Products, public comments on an advance notice of proposed rulemaking that was based on that statement, and public comments on the notice of proposed rulemaking for OTC topical antimicrobial drug products. (See the **Federal Register** of January 6, 1978; 43 FR 1210.) The agency's proposals concerning the use of other OTC diaper rash drug products are being published elsewhere in this issue of the **Federal Register**. These proposals are part of the ongoing review of OTC drug products conducted by FDA.

DATES: Written comments, objections, or requests for oral hearing on the proposed rulemaking before the Commissioner of Food and Drugs by December 17, 1990. The agency is allowing a Period of 180 days for comments and objections instead of the normal 60 days for the following reasons: (1) The concurrent publication of four rulemakings regarding OTC diaper rash drug products and (2) this document contains the agency's initial evaluation of the submissions of data on OTC diaper rash drug products that were made to, but not reviewed by, the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel). New data by June 20, 1991. Comments on the new data by August 20, 1991. Written comments on the agency's economic impact determination by December 17, 1990.

ADDRESSES: Written comments, objections, new data, or requests for oral hearing to the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: William E. Gilbertson, Center for Drug Evaluation and Research (HFD-210), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-295-8000.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of September 7, 1982, FDA published, under § 330.10(a)(6) (21 CFR §330.10(a)(6)), advance notices of proposed rulemaking and reopened the administrative records for OTC topical antifungal drug products (47 FR 39464), topical antimicrobial drug products (47 FR 39406), external analgesic drug products (47 FR 39412), and skin protectant drug products (47 FR 39436) to allow for consideration of a statement on OTC drug products for the treatment of diaper rash prepared by the Miscellaneous External Panel, which was the advisory review panel responsible for evaluating data on the active ingredients used for the treatment of diaper rash. Interested persons were invited to submit comments by December 6, 1982. Reply comments in response to comments filed in the initial comment period could be submitted by January 5, 1983.

In the **Federal Register** of December 28, 1982 (47 FR 57738), in response to a request for an extension of time, the comment period and reply comment period for OTC topical antimicrobial drug products were extended to February 4, 1983, and to March 7, 1983, respectively.

In accordance with § 330.10(a)(10), the data and information considered by the Panel were put on public display in the Dockets Management Branch (HFA-305), Food and Drug Administration (address above), after deletion of a small amount of trade secret information.

Four drug manufacturers, one trade association, and one manufacturer of diapers submitted comments. Most of these comments are general in scope and were submitted to more than one of the four rulemakings mentioned above. In those cases where the same comments were submitted to more than one rulemaking, the comments are being addressed only once—in the notice of proposed rulemaking to amend the notice of proposed rulemaking for OTC skin protectant drug products. In addition, this document addresses comments on products containing topical antimicrobial ingredients used for diaper rash that were submitted by two drug manufacturers in response to the advance notice of proposed rulemaking for OTC topical antimicrobial drug products (see the **Federal Register** of September 13, 1974; 39 FR 33103) and the tentative final monograph for OTC topical antimicrobial drug products (see the **Federal Register** of January 6, 1978; 43 FR 1210). Copies of the comments received are on public display in the Dockets Management Branch (address above).

The Panel provided a general statement on OTC drug products for the treatment of diaper rash, but did not review individual ingredients nor develop labeling for diaper rash drug products. The agency is aware that a number of diaper rash drug products are labeled for both the treatment and prevention of diaper rash. Therefore, the agency is expanding the scope of this rulemaking to include drug products labeled for both or either use.

In this notice of proposed rulemaking, FDA responds to public comment and states for the first time its position on OTC topical antimicrobial drug products for the treatment or prevention of diaper rash. Final agency action on this matter will occur with the publication at a future date of a final rule relating to OTC topical antimicrobial drug products for use in diaper rash. Other documents concerning the use of OTC topical antifungal drug products, OTC external analgesic drug products, and OTC skin protectant drug products for the treatment or prevention of diaper rash are being published separately, elsewhere in this issue of the **Federal Register**. This proposal constitutes FDA's tentative adoption of the Panel's statement on OTC topical antimicrobial drug products for use in diaper rash as modified on the basis of the comments received and the agency's independent evaluation of the Panel's statement.

The OTC drug procedural regulations (21 CFR 330.10) now provide that any testing necessary to resolve the safety or effectiveness issues that formerly resulted in a Category III classification, and submission to FDA of the results of that testing or any other data, must be done during the OTC drug rulemaking process before the establishment of a final monograph. Accordingly, FDA will no longer use the terms "Category I" (generally recognized as safe and effective and not misbranded), "Category II" (not generally recognized as safe and effective or misbranded), and "Category III" (available data are

insufficient to classify as safe and effective, and further testing is required) at the final monograph stage, but will use instead the terms "monograph conditions" (old Category I) and "nonmonograph conditions" (old Categories II and III). This document retains the concepts of Categories I, II, and III at the tentative final monograph stage.

The agency advises that the conditions under which the drug products that are subject to this monograph would be generally recognized as safe and effective and not misbranded (monograph conditions) will be effective 12 months after the date of publication of the final monograph in the Federal Register. On or after that date, no OTC drug product that is subject to the monograph and that contains a nonmonograph condition, i.e., a condition that would cause the drug to be not generally recognized as safe and effective or to be misbranded, may be initially introduced or initially delivered for introduction into interstate commerce unless it is the subject of an approved application. Further, any OTC drug product subject to this monograph that is repackaged or relabeled after the effective date of the monograph must be in compliance with the monograph regardless of the date the product was initially introduced or initially delivered for introduction into interstate commerce. Manufacturers are encouraged to comply voluntarily with the monograph at the earliest possible date.

If the agency determines that any labeling for a condition included in the final monograph should be implemented sooner than the 12-month effective date, a shorter deadline may be established. For example, if a safety problem is identified for a particular nonmonograph condition, a shorter deadline may be set for removal of that condition from OTC drug products.

All "OTC Volumes" cited throughout this document refer to the submissions made by interested persons pursuant to the call-for-data notices published in the Federal Register of November 16, 1973 (38 FR 31697) and August 27, 1975 (40 FR 38179) or to additional information that has come to the agency's attention since publication of the advance notices of proposed rulemaking. The volumes are on public display in the Dockets Management Branch (address above).

I. The Agency's Tentative Conclusions on the Comments

The agency has reviewed the comments submitted to this rulemaking and, as noted above, determined that most of the comments were submitted to more than one of the four rulemakings related to OTC diaper rash drug products. The majority of the comments are general in scope or deal primarily with the use of skin protectant active ingredients. The agency has decided to address all of these general comments in a single rulemaking, which is the notice of proposed rulemaking to amend the tentative final monograph for OTC skin protectant drug products, published elsewhere in this issue of the Federal Register. Those comments are incorporated by reference into this rulemaking.

A. General Comments on Antimicrobial Ingredients in Diaper Rash Drug Products

1. Several comments stated that OTC topical antimicrobial ingredients can provide rational therapy to prevent or treat diaper rash by reducing the level of harmful bacteria present in the diapered area. One comment suggested that indications for an antimicrobial-containing diaper rash drug product should include such statements as "helps kill germs associated with diaper rash" and "helps kill germs that may aggravate diaper rash." Another comment stated that secondary infections caused by bacteria or fungus may accompany diaper rash as complications, and these infections should be diagnosed and treated by a physician. The comment contended that OTC drug products are useful to protect the skin from the irritation of urine and feces, but not to treat the secondary infection that may accompany the irritation.

The agency agrees with the last comment. Only ordinary, mild diaper rash (in which the skin is reddened but not broken) should be treated with OTC drugs. A rash in the diaper area that does not clear up in a reasonable amount of time may indicate the presence of a secondary bacterial or fungal skin infection (Refs. 1 and 2). The agency believes that these conditions should not be treated with OTC drugs and that an infant with a suspected bacterial infection in the diaper area or a diaper rash that has persisted a week or more should be taken to a physician for appropriate diagnosis and therapy. Some physicians recommend treating bacterial infections in the diaper area with systemic antibiotics (Refs. 2, 3, and 4), which require a physician's prescription. (See fungal infections in diaper rash as discussed in the notice of proposed rulemaking for OTC antifungal drug products published elsewhere in this issue of the Federal Register.)

Diaper dermatitis is a convenient term used to encompass a wide range of inflammatory processes that occur in the diaper area (Ref. 5). Diaper dermatitis includes diverse disorders which appear in the diaper area, and identifying the etiology of a diaper rash and selecting the therapeutic agent are difficult even for a physician (Refs. 2 through 6). Schanzer and Wilkin (Ref. 2) noted that the diagnostic range includes irritant dermatitis, allergic dermatitis, intertrigo, seborrheic dermatitis, atopic eczema, candidiasis, psoriasis, scabies, miliaria, bullous impetigo, and granuloma gluteal infantum. These authors developed a full page flow chart to be used by family physicians for diagnosing and treating diaper dermatitis before referring a patient to a dermatologist.

The agency agrees with these experts (Refs. 2 through 6) that lay persons do not have adequate medical background or training to diagnose and treat such infections or other conditions in the diaper area. The agency believes that a physician should be consulted for diagnosis and appropriate therapy for the different types of diaper dermatitis described above, including bacterial infection. Accordingly, the agency believes the claim "treats infection" or any similar claim is inappropriate for OTC diaper rash drug products and should be classified Category II.

As to general antimicrobial claims, such as "helps kill germs associated with diaper rash," the agency notes that a number of diaper rash products submitted to the OTC drug review contain antimicrobial ingredients such as boric acid, calcium undecylenate, methylbenzethonium chloride, sodium propionate, and triclosan. These products include antimicrobial labeling such as "antiseptic," "for diaper rash: acts as antiseptic to help fight staph germs and other bacteria," "kills millions of diaper rash germs," "kills bacteria that cause diaper rash and odor," and "medicated formula, inhibits the growth of bacteria." These claims are discussed below.

The agency has evaluated the role of bacteria in causing or aggravating diaper rash. As noted above, secondary infections, usually due to *Staphylococcus aureus (S. aureus)*, streptococci, or *Candida albicans (C. albicans)* (Ref. 2), may develop as a complication of diaper rash. It is much less clear, however, what changes in the normal skin flora may accompany diaper rash that could predispose to the development of a secondary infection or whether the use of OTC antimicrobial ingredients is effective in preventing secondary infections. The data submitted do not adequately address these questions because many of the

studies were in vitro studies on the antibacterial activity of the ingredient and did not address the issue of bacterial involvement in diaper dermatitis or demonstrate clinical effectiveness. Furthermore, even the clinical studies which demonstrated improvement did not include microbiological cultures from the treated infants to determine whether the improvement could be attributed to the antimicrobial ingredient. The studies are discussed as part of the individual ingredient evaluations later in this document.

The agency has identified several microbiological studies in which infants with and without diaper rash were compared to determine the role of bacteria in causing diaper rash (Refs. 7 through 11). In some of the studies described below, the normal infants have similar and sometimes higher total bacterial counts or larger number of species isolated than the infants with diaper rash. It could be argued, therefore, that proliferation of bacteria does not appear to be a cause of diaper rash. One persistent finding in many of the studies is that the counts of *S. aureus* are higher in the infants with diaper rash than in the normal control infants or the after-cure infants.

Brookes, Hubbert, and Sarkany (Ref. 7) studied 60 infants on their regular well baby visits to a family health clinic to determine the incidence of diaper rash and to clinically evaluate early cases. A wide range of bacteria was found on the skin of both groups of infants with a total of 9 bacterial species for the normal group and 7 for the diaper rash group. However, no significant difference was found in the microflora of the skin in the diaper area of 25 infants with diaper dermatitis and 35 normal infants. Overall, an average of 2.6 species were cultured from the normal infants and 2.4 bacterial species from the infants with diaper rash. The incidence of *S. aureus* (or coagulase positive staphylococci) was 20 percent in both groups. The authors added that they had included in their study only infants in which diaper rash was an incidental finding and concluded that the state of the bacterial skin flora plays no etiological role in early cases of diaper rash.

Brown, Tyson, and Wilson (Ref. 8) conducted a bacteriological survey of the types of organisms found in wet diapers, soiled diapers, and from swab cultures taken from 81 children with diaper rash and 25 children not having rash. Thirteen species of bacteria were isolated from the infants with diaper rash and 10 species from the control infants. *Escherichia coli* (*E. coli*) was the most frequent isolate, occurring in all 25 of the control infants and in 77 (95 percent) of the infants with diaper rash. Major differences in the two groups occurred with *S. aureus* which was isolated from 52 (64.2 percent) of the infants with diaper rash but only from 1 (4 percent) of the infants not having a rash. Beta hemolytic streptococci were isolated from 21 (25.9 percent) of the infants with diaper rash and from 2 (8 percent) of the control infants. *Streptococcus viridans* (*S. viridans*) occurred frequently in both groups, but was still more prevalent in the infants with diaper rash (81.5 percent) than in the control infants (48 percent). Six children in the control group had previously been studied while they had diaper rash; *S. aureus* was isolated from two children. The organisms were not isolated following recovery.

Pittillo et al. (Ref. 9) studied the microbial skin flora of the diaper area of 10 infants without a recent history of diaper dermatitis and 10 infants affected with diaper dermatitis. Eleven different bacterial species were recovered from the normal group, and nine from the group with diaper rash. Overall, an average of 2.4 species was cultured from the infants with diaper rash and 2.9 species from the normal infants. The incidence of *E. coli* was the most striking difference, occurring in 8 out of 10 of the normal infants but in only 3 out of 10 of the infants with diaper rash. *S. aureus* occurred in 5 out of 10 of the infants with diaper rash, but occurred only in 3 of 10 of the normal infants.

Leyden and Kligman (Ref. 10) conducted a quantitative microbiological survey of multiple sites in the diaper area in 40 normal infants and 100 infants with various forms of diaper dermatitis, classified clinically into the following categories: chafing dermatitis (20 percent), atopic dermatitis (24 percent), moniliasis (25 percent), moniliasis with disseminated "id" (15 percent), seborrheic dermatitis (10 percent), psoriasis (2 percent), and undecided (4 percent). The authors stated that chafing (irritant) rash is the most prevalent and the least serious form of diaper dermatitis, and it is usually treated without medical advice. Although *S. aureus* was not recovered from any site of the normal infants, it was frequently isolated from the infants with diaper dermatitis. *S. aureus* occurred in all of the cases of atopic dermatitis type diaper rash and made up 80 percent of the total flora. *S. aureus* also was frequently found at lower counts in the other types of diaper dermatitis including 50 percent of the infants with chafing dermatitis in which it made up 20 percent of the total flora when present. The authors considered *S. aureus* to be a secondary invader in atopic dermatitis in the diaper area. Conversely, because the level of *S. aureus* was lower in chafing diaper dermatitis, Leyden and Kligman concluded that microbes appear to play no role in the chafing form of diaper dermatitis, which they considered to result from friction and maceration of constantly wet skin.

Montes et al. (Ref. 11) obtained bacterial cultures from the diaper area of 35 infants with diaper dermatitis and from 25 normal controls. A total of 14 species of microorganisms were recovered in the diaper rash group, 13 in the normal control group. The average number of species per infant was 2.54 for the diaper rash group, and 2.36 for the normal control group. The authors found that *S. aureus* and *Aerobacter aerogenes* occurred significantly more often in the diaper rash group than in the normal control group. *S. aureus* was recovered from 42.8 percent of the infants with diaper rash, and 28 percent of the normal control infants. For the other 12 species of bacteria recovered in the study, the normal control group had just as high, if not higher, an incidence as the diaper rash group. There was no significant difference in the total microbial counts of the two groups.

The agency has determined that more information is needed to clarify what, if any, role specific bacteria such as *S. aureus* play in ordinary, mild diaper rashes (where the skin is reddened but not inflamed or infected) that would be suitable for OTC drug treatment.

Leyden and Kligman (Ref. 10) felt that *S. aureus* had no role in the chafing form of diaper dermatitis. Leyden (Ref. 5) states that in diaper dermatitis colonization of dermatitic skin by *S. aureus* occurs frequently, and the more intense the inflammation, the more likely *S. aureus* colonization will occur. When *S. aureus* proliferates to high levels, secondary infection can be shown to occur. Weston, Lane, and Weston (Ref. 6) discussed the Leyden and Kligman study (Ref. 10) and stated that the role of colonization with *S. aureus* is not clear from that study. They noted that bacteriostatic agents, such as methylbenzethonium chloride, have been demonstrated in several studies to reduce the frequency of diaper rash. These authors concluded that, while quantitative increase in bacteria and bacterial products may possibly be involved in the genesis of diaper dermatitis, there is no firm proof that bacteria account for the dermatitis.

Pittillo et al. (Ref. 9) suggested that the inflammation that occurs in diaper rash tended to decrease the number of bacteria found in infants with diaper rash as compared to normal infants. Leyden, Marples, and Kligman (Ref. 12) have noted just the opposite with *S. aureus*, namely that *S. aureus* thrives better in inflamed skin, and that corticosteroids are effective therapy for atopic dermatitis with *S. aureus* involvement because suppression of inflammation leads to unfavorable conditions for *S. aureus*. Therefore, it is possible in the case of diaper rash that the accompanying inflammation inhibits the normal flora while it allows the overgrowth of potential pathogens that may cause secondary infections. Any antimicrobial treatment should counteract this shift, not intensify it. Also, as Leyden, Marples, and Kligman (Ref. 12) state, antibiotic therapy to treat infection in the diaper area should be limited to 1 week because prolonged antibiotic therapy may invite colonization with resistant organisms or new pathogens. Therefore, the agency has concerns about the safety and efficacy of simply using antimicrobials (antibacterials or antibiotics) in the diaper area just for the purpose of generally reducing the microflora count. The agency believes that regular use could even worsen the problem if the antimicrobial caused undesirable changes in the balance of bacteria in the skin flora.

The studies discussed above show that there are different theories on the role of bacteria in causing or aggravating diaper rash. It appears to be generally accepted that primary chafing (irritant) diaper dermatitis which results from friction and maceration of constantly wet skin (Refs. 2, 3, 5, and 10) is the most common type of diaper rash (Refs. 2, 4, 5, 6, and 10), the least serious (Ref. 10), and the type usually treated with OTC drugs (Ref. 10). The agency believes that this condition is best treated by changing diapers more frequently and by applying a skin protectant drug product for protection of the area from the irritant(s). Questions that remain to be answered are whether the presence of antimicrobial ingredients in OTC diaper rash drug products serves a useful function in treating this type of diaper rash and in preventing secondary infection and other complications that might occur. Based upon the available data, the agency classifies the use of topical antimicrobial ingredients and the claims mentioned above for OTC diaper rash drug products in Category III.

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2. Several submissions to the Antimicrobial I Panel (Ref. 1), the Antimicrobial II Panel (Ref. 2), and the Miscellaneous External Panel (Refs. 3 and 4) were for products containing antimicrobial active ingredients with labeling claims for ammoniacal diaper dermatitis such as "combats ammonia-forming bacteria that can be a major cause of diaper rash and odor," "eliminates cause of diaper rash (ammonia dermatitis)", and "aids in preventing the occurrence of ammoniacal dermatitis when used regularly." A number of the submissions (Refs. 2 and 3) included controlled clinical studies on a series of diaper rash products containing methylbenzethonium chloride in both topical drug products and products for impregnating diapers. One submission (Ref. 4) included clinical studies and in vitro data for a diaper rash cream containing benzethonium chloride. Several submissions (Ref. 1) included in vitro data on triclosan and on a triclosan-containing baby powder. These studies and data are discussed as part of the individual ingredient evaluations later in this document.

According to many of the submissions, ammonia is produced from urea in urine by the action of certain microorganisms; this ammonia causes ammoniacal diaper dermatitis; and antimicrobial agents such as methylbenzethonium chloride, benzethonium chloride, or triclosan, through their antibacterial activity, reduce the number of these microorganisms and thereby reduce the amount of ammonia produced. These submissions included published articles that discussed this condition, and the articles were generally based on Cooke's 1921 theory of ammoniacal dermatitis (Ref. 5). Cooke noted that ammonia was first implicated in the etiology of diaper dermatitis when Southworth (1913) and Zahorsky (1915) noted that a strong ammonia odor in diapers often accompanied the clinical disease. Cooke (Ref. 5) isolated urea-splitting bacteria which he found in the stool cultures of 31 infants and children, from age 1½ months to 4 years old, who had diaper dermatitis. He suggested the name *Bacillus ammoniagenes* for the organism which was later reclassified as *Brevibacterium ammoniagenes* (*B. ammoniagenes*). Cooke recognized that other organisms are capable of splitting urea to form ammonia—including *S. aureus*, *Sarcina lutea*, and *Bacillus proteus*—although he seldom found these other organisms in the stools examined in his study. Cooke applied *B. ammoniagenes* cultures with and without 1 percent urea to his arm under occlusion, and reported that erythema developed in the areas where the organisms and urea were applied, but there was no erythema in the areas where only the organisms were applied. Cooke concluded that the skin lesions were caused by the ammonia and not by the bacteria. Although Cooke did not attempt to reproduce the lesions experimentally on infants, he concluded that the evidence was sufficient to show that ordinary diaper rash is a dermatitis caused by ammonia being produced. Cooke concluded that the ammonia was produced by *B. ammoniagenes* that infest the diaper from the feces. He determined that, in the urine soaked diaper, this bacterium is able to decompose the urinary urea into free ammonia by the following reaction:

$$CO(NH_2)_2 + 2H_2O = (NH_4)_2CO_3 = 2NH_3 + H_2O + CO_2$$

Cooke stated that formation of ammonia from urea by bacteria must be

accomplished by the bacterial enzyme urease, but he was unable to extract urease. Cooke therefore concluded that the inhibition of the ammonia formation depended on the inhibition of bacterial growth rather than upon inhibition of urease activity. Cooke further suggested that "Since the dermatitis in these cases is a result of ammonia formed by bacterial action on urea in the diaper, it follows that the simplest and most logical method of prevention is to treat the diaper and not the infant." Cooke recommended the use of three nonvolatile antiseptics to impregnate the diaper in ammonia dermatitis: (i) A 1:5,000 solution of mercuric chloride, (ii) a 1:5,000 solution of mercuric iodide, and (iii) a 1:20 solution of boracic acid. In 1947, Benson et al. (Ref. 6), attempting to use a less toxic antiseptic than those Cooke recommended, impregnated diapers with a quaternary ammonium compound, namely para di-isobutyl-cresoxy-ethoxy-ethyl di-methyl benzyl ammonium chloride monohydrate, later named methylbenzethonium chloride.

The agency notes that Cooke's theory of ammoniacal dermatitis was originally well accepted, published in several text books (Refs. 7, 8, and 9), and went unchallenged until more recent studies raised questions regarding this theory. Later researchers such as Pratt (Ref. 10) described other rashes in the diaper area that were not related to the wearing of diapers. Weston, Lane, and Weston (Ref. 11) listed 23 other skin conditions occurring in the diaper area that required differential diagnosis from diaper-caused diaper rash. Furthermore, whereas Cooke had concluded that all diaper-caused rashes resulted from ammonia irritation, later researchers such as Burgoon, Urbach, and Grover (Ref. 12) began to suggest that diaper-caused dermatitis was not a single entity, but could result from several factors, such as (1) maceration and sweat retention from continuous contact with a wet diaper, especially when used with an impervious diaper cover, (2) primary irritation reaction from contact with feces, (3) allergic reactions to detergent soap preparations, and (4) mechanical irritation from the rubbing of a tight wet diaper. Finally, Leyden et al. (Ref. 13) concluded that ammonia liberated by the action of *B. ammoniagenes* was clearly not an important causative factor in diaper dermatitis and perhap not a factor at all.

Leyden et al. (Refs. 13 and 14) cultured squeezings from the morning diapers of 63 normal infants and 18 infants with a chafing, irritant type diaper dermatitis ("ammoniacal dermatitis," not candida infections or other dermatitis) and isolated a variety of organisms from all of the infants. The results showed that the presence of a strong ammonia-producing organism did not correlate with the presence of diaper dermatitis. Twelve (66.7 percent) of the 18 infants with diaper dermatitis had organisms capable of liberating ammonia in 24 hours, compared to 12 (19.0 percent) of the 63 infants free of any rash. However, strongly positive urea-splitting large colony diphtheroids capable of liberating ammonia in 4 to 6 hours, which the authors identified as similar to Cooke's *B. ammoniagenes*, were rarely recovered. Nevertheless, the *B. ammoniagenes* prevalence was five times as frequent in infants with diaper dermatitis (16.6 percent) than in normal infants (3.2 percent). Conversely, the total of strongly positive urea-splitting isolates capable of liberating ammonia in 4 to 6 hours was found to be slightly less in those infants with diaper rash (44.4 percent) than in normal infants (52.3 percent). Leyden (Ref. 14) concluded that neither the prevalence nor the density of urea-splitting organisms was significantly different for either population.

Leyden et al. (Ref. 13) also determined the ammonia levels, both free ammonia and total ammonia after incubation with urease, in the squeezings from the morning diapers of 82 normal infants and 26 infants with diaper rash. The mean total ammonia after incubation with urease was found to be slightly higher in the infants with diaper rash (7,803 parts per million (ppm)) than in the normal infants (7,556 ppm). Conversely, the level of free ammonia tended to be higher in the normal infants. The mean level of free ammonia in normal infants was 465 ppm and in infants with diaper dermatitis was 402 ppm. A total of 27 percent of the infants with diaper dermatitis had levels of free ammonia in excess of 500 ppm as compared to 22 percent of the normal infants. A total of 12 percent of infants with diaper rash and 22 percent of normals had a level of 600 ppm or greater. The authors concluded that there was no significant difference between the two groups.

Finally, Leyden et al. (Ref. 13) found that urine containing 1.6 percent ammonia (five times the mean of infants with diaper dermatitis) failed to produce diaper rash when placed on the skin of the buttocks of 10 infants under an occlusive dressing for 24 hours. Additional, more challenging skin studies were conducted on the arms of adult volunteers. Repeated application for 5 days of 1.6 percent ammoniated urine and 2.5 percent or 5 percent ammonium hydroxide also failed to induce damage on normal skin of 10 adults. However, repeated application of 10 percent ammonium hydroxide was able to produce erythema in 1 of 10 adult subjects after 48 hours of occlusion. Also, repeated applications (for 72 hours) of urine with both 0.5 percent and 0.05 percent ammonium hydroxide were able to produce erythema on scarified adult skin. Because 27 percent of the infants with diaper rash and 22 percent of the normal infants had a level of 0.05 percent or greater ammonia in their urine, Leyden et al. concluded that ammonia could possibly play a secondary role in aggravating already damaged skin, but that by itself it does not initiate a dermatitis. The authors state "In this light, we would regard measures aimed at acidifying urine, or the application of antimicrobial agents for the skin to diapers, as unsound and superfluous prophylactic practices."

Berg, Buckingham, and Stewart (Ref. 15) and Buckingham and Berg (Ref. 16) studied the roles of feces and urine, particularly ammonia, in the etiology of diaper dermatitis using the hairless mouse cutaneous primary irritation test and appeared to come to somewhat different conclusions than Leyden et al. (Ref. 13). For example, while noting that the work of Leyden et al. suggested that ammonia per se was not a primary factor in the induction of diaper dermatitis, these authors nevertheless stated that "While it is generally accepted that several etiologies are involved, the clear clinical association between the odor of ammonia on diapers and the presence of diaper dermatitis remains as strong today as it was at the turn of the century when ammonia was first assigned a role in this malady," (Ref. 15). In the study on the irritancy of infant urine, Berg, Buckingham, and Stewart (Ref. 15) found that "Infant urine did not cause skin irritation when patched on hairless mice for 48 hours, but skin damage did become apparent after continuous exposure for 10 days," and therefore concluded that "While the irritation potential of urine appears to be low, long-term exposure of skin to urine may lead to irritation." The authors concluded that because "diapered infants are almost constantly exposed to urine, it is reasonable to postulate a primary role for urine in the etiology of some cases of diaper dermatitis." Berg, Buckingham, and Stewart also found that when infant feces and urine were combined in a patch test, the irritancy was substantially higher than when either feces or urine were tested alone.

They determined that this synergistic irritancy was the result of the enzyme action of urease in the feces producing ammonia from urea in the urine, but noted that the increase in irritancy appeared to be a function of the increase in pH rather than an effect of ammonia per se. Therefore, while the authors did suggest that ammonia played an indirect role in diaper dermatitis involving an interaction between urine and feces, they concluded that the irritancy to the skin can be directly attributed to fecal enzymes, particularly proteases and lipases, that become more active and thus more damaging as the pH increases.

Based on the above findings, the agency is unable to determine whether Cooke's original theory of ammonia diaper rash has been completely refuted by Leyden et al. (Ref. 13) and Leyden (Ref. 14) or whether it has been confirmed by Berg, Buckingham, and Stewart (Ref. 15) and Buckingham and Berg (Ref. 16) with a slight revision to the effect that ammonia does not directly cause the dermatitis, but ammonia, being highly alkaline, changes the pH and activates other irritating substances in the urine and feces to cause the dermatitis.

The Berg, Buckingham, and Stewart study (Ref. 15) and the Buckingham and Berg study (Ref. 16) only pertained to patch testing of mice and may not be directly applicable to diapers used on babies. Also, the Leyden et al. diaper juice tests (Ref. 13) only pertained to ammonia levels in diaper squeezings and did not test for pH, proteases, or lipases. Accordingly, the agency is unable to conclude that urease-producing bacteria growing in urine-soaked diapers could not also cause the same chain reaction (bacteria-urease-urine-ammonia-high pH-activated toxic fecal enzyme-skin irritation) that Berg, Buckingham, and Stewart attribute to the same urease-producing bacteria growing in the intestine.

The agency believes that Cooke's ammonia theory of diaper rash, while perhaps not yet disproven, has been sufficiently questioned by these more recent studies and that the theory may not be as simple and straightforward as Cooke originally proposed. Furthermore, none of the data submitted by the comments is sufficient to answer the specific points raised by these newer studies. The agency has determined that the issues raised by the newer studies need further clarification and that there does not appear to be a generally recognized theory at this time to support OTC treatment or prevention of ordinary, mild diaper rash with antimicrobial drug products. Therefore, the agency is classifying in Category III those antimicrobial claims that are based upon the activity of diaper rash drug products against specific urea-splitting bacteria or are based upon proposed mechanisms of action such as Cooke's ammonia theory of diaper rash. Before claims of this type can be classified in Category I for antimicrobial-containing diaper rash drug products, further data are needed to demonstrate the effects, if any, of topical antimicrobials on the urea-splitting bacteria present in the microbial flora of infant skin in the diaper area. In addition, data are needed to show the amount of ammonia in the diaper, and whether any such changes in the amount of ammonia present correlate with changes in diaper dermatitis. Any claims concerning this ammonia theory need to be justified by clinical studies on infants that include bacteriological studies to correlate a reduction in ammonia-producing bacteria with a clinical improvement in the diaper rash.

Antimicrobial ingredients with claims for ammoniacal diaper dermatitis have been evaluated in the discussions of the ingredients benzethonium chloride, methylbenzethonium chloride, and triclosan. (See comments 6, 11, and 16 below.) Diaper rash products used to impregnate diapers with antimicrobial ingredients are also discussed below. (See comment 4 below.)

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(2) OTC Volumes 070074, 070075, 070076, 070078, 070079, 070080, and 070081.

(3) OTC Volumes 160242, 160243, 160244, 160245, 160246, 160247, and 160427.

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3. One comment stated that active ingredients that are not classified as skin protectants, when used in diaper rash drug products, should have a record of safety especially with regard to use on infants' skin.

The agency agrees with the comment that ingredients used in OTC diaper rash drug products should have a proven safety record with regard to use on infants' skin, especially when used for prolonged periods of time and under occlusion. Safety is a particular concern with topical antimicrobial ingredients because of serious or even fatal poisoning which may result from transcutaneous absorption. Reports have shown that mercury, phenol, resorcin, boric acid, and hexachlorophene can be very toxic and cause death in infants, even when applied externally (Ref. 1). Even drugs considered safe for use in adults may be of concern when used on infants because, as Barnett (Ref. 2) pointed out, the skin of infants differs in many fundamental respects from that of adults. Because infant skin is just half as thick as adult skin (Ref. 3), and because of the high surface-to-volume ratio and the peculiarities of systemic metabolism and detoxification in very young children, the risk of systemic effects from topical preparations is increased (Ref. 4). Major differences exist in drug disposition between pediatric and adult patients, and a number of enzyme systems are deficient or even absent in the neonate (Ref. 5). For example, immaturity of the enzyme hepatic glucuronyl transferase results in diminished conjugation of chloramphenicol to form the inactive acid glucuronide (Ref. 5). Another antibiotic (novobiocin) directly inhibits hepatic glucuronyl transferase in neonates, resulting in an accumulation of metabolic products toxic to the baby (Ref. 5).

The Antimicrobial I Panel, in its advance notice of proposed rulemaking for OTC topical antimicrobial drug

products (September 13, 1974; 39 FR 33103), recommended warnings against the use of several antimicrobial ingredients on infants under 6 months of age until additional studies were submitted to demonstrate safety in animals deficient in these detoxification mechanisms. These ingredients included triclocarban, cloflucarban, triclosan, phenol, and chloroxylenol, all of which are metabolized and eliminated from the body by glucuronide or sulfate conjugation in the liver. As stated in the tentative final monograph for OTC topical antimicrobial drug products (January 6, 1978; 43 FR 1210), the agency concurs with these recommended warnings and further believes that products marketed with diaper rash claims should be safe for use on infants of all ages.

Diaper rash drug products are used on an area of the body and under conditions that favor percutaneous absorption and increased susceptibility of the skin to irritants. The inguinal region, urorectal area, scrotum, and female genitalia are sites of application with enhanced percutaneous absorption (Refs. 6 and 7). Diseased or damaged skin may also result in the loss of barrier function of the stratum corneum and increase percutaneous absorption (Refs. 6 and 7). The increased temperature and moisture that are produced by the occlusion of a diaper, rubber pants, or clothing will enhance skin permeability and percutaneous absorption (Refs. 8, 9, and 10). Continuous exposure to urine also increases permeability of skin, suggesting that infant skin in the diaper area may become more permeable to ingredients that might be present in the diaper environment (Ref. 9). Wester and Maibach (Refs. 6 and 7) state that when some or all of these parameters are involved, absorption from topical administration is enhanced. The hydration and maceration of skin that is promoted by the semioccluded diaper environment is also known to increase the susceptibility of the skin to many irritants (Ref. 11). Further, infants may become sensitized to regular use of topically applied antibacterial agents which may result in inflammation or allergic contact dermatitis that may aggravate or even induce a rash (Refs. 3, 4, and 12). Thus, an evaluation of each component in diaper rash drug products for sensitization and irritation potential is necessary.

Current agency regulations in 21 CFR 369.20 contain recommended warnings against use on large areas of the body for several OTC topical antimicrobial drugs, i.e., boric acid, carbolic acid (phenol), cresols, and mercury preparations. Because diaper rash drug products are applied over a relatively large percent of the surface area of an infant's body, products containing these antimicrobials would not be appropriate for treating or preventing diaper rash.

For antimicrobial ingredients to be placed in Category I for use on infants in OTC diaper rash drug products, adequate data demonstrating safety addressing the concerns raised in this document, as well as adequate efficacy data, are needed. Discussion of the safety of individual antimicrobial ingredients considered in this rulemaking appears in Part I comments 5 to 19 below.

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4. One company submitted information on three types (tablets, granules, and concentrated solution) of laundry products containing methylbenzethonium chloride to be dissolved in water for use as a final rinse to impregnate diapers. These products were labeled with the claim "eliminates cause of diaper rash (ammonia dermatitis)" (Ref. 1). Another company submitted information on a general disinfectant product containing benzalkonium chloride with directions to dilute for use as a "final sanitizing diaper rinse" (Ref. 2). However, the product did not bear any specific claims about diaper rash. Another company submitted information on moist disposable towelettes impregnated with benzalkonium chloride and labeled for use to clean the baby when changing diapers to help "alleviate baby's minor diaper irritations," (Ref. 3).

The agency notes that laundry products with antimicrobial claims are regulated as disinfectants by the Environmental Protection Agency (EPA), which has the following policy: An EPA-registered rinse for diapers may only claim to control, on the treated diaper, the microorganism that causes diaper rash (Ref. 4). FDA has jurisdiction over products used on humans. Therefore, depending on the label claims, laundry products regulated by EPA may also be regulated under the Federal Food, Drug, and Cosmetic Act (the act) as drug products.

In determining whether a product is a drug, FDA considers the properties of the product, its intended uses, and the definition of the term "drug" in the act. Diaper rinses intended for use in the prevention or treatment of diaper rash are drugs within the meaning of section 201(g) of the act [21 U.S.C. 321(g)]. The term "drug" is defined in section 201(g)(1) as, among other things, "* * * articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease * * * and * * * articles (other than food) intended to affect the structure or any function of the body * * *." A drug generally is a chemical or a combination of chemicals in liquid, paste, powder, or other drug dosage form that is ingested, injected, or instilled into body orifices, or rubbed or poured onto the body in order to achieve its intended medical purpose.

A diaper rinse is a chemical entity or a combination of chemical entities intended for in vivo use. An article which is a drug within the meaning of section 201(g) of the act does not lose its status as a drug merely because its directions for use recommend application by means of a household article such as a cotton ball or swab, or, in this case, an infant's diaper. In fact, a

unique method of delivery of a drug product may cause the article to be a "new drug" under the meaning of section 505 of the act (21 U.S.C. 355) if the dosage form is not one that is generally recognized as safe and effective for this use.

Based upon the above, the agency has the following comments on the specific products that were submitted. The three diaper rinse products containing methylbenzethonium chloride (Ref. 1) are drugs based upon their intended use as expressed in the labeling statements: "Eliminates cause of diaper rash (ammonia dermatitis)," "* * * diaper rash (ammonia dermatitis) is due to irritating ammonia released by the bacterial decomposition of the baby's urine," "* * * eliminates the cause of diaper rash by checking formation of urinary ammonia in wet diapers * * *," "Use only as a final, clean rinse," "* * * methylbenzethonium chloride that fights the bacteria that cause ammonia to form * * *." The active principle in these products is the chemical methylbenzethonium chloride. Its mode of action is further delineated under the section entitled Efficacy Evaluation in the company's submission (Ref. 1), which states in part:

> * * * methylbenzethonium chloride, released from ointment, cream and powder bases or from impregnated diapers, can effectively and safely ameliorate and prevent certain forms of diaper rash and does so presumably by killing microorganisms in urine and feces that produce ammonia and other (as yet, unspecified) irritating agents.

The agency does not, however, consider the product containing benzalkonium chloride (Ref. 2) to be a drug within the meaning of section 201(g) of the act as far as its intended use can be determined from the labeling or other submitted material. Although the product's label declares the active ingredient as alkyl dimethybenzylammonium chlorides (benzalkonium chloride), and the labeling directions recommend the product "For final sanitizing diaper rinse * * *" there is no indication in the product's labeling that it is intended to prevent or to treat diaper rash. It appears from the product's labeling and other backgound information that the product is intended solely for the disinfection or sanitization of inanimate objects, including diapers, and not for the treatment of a disease or condition.

The agency considers the baby wipe towelettes containing benzalkonium chloride (Ref. 3) to be a drug within the meaning of section 201(g) of the act because of the statement in its labeling: "helps alleviate baby's minor diaper irritations * * *." Moreover, the manufacturer's submission included a controlled clinical study to evaluate the effectiveness of using these baby wipe towelettes for diaper rash among other conditions and the study was specifically cited and discussed in the efficacy summary in the submission (Ref. 3). The manufacturer's action supports the position that the article is a drug intended for use in the treatment of diaper rash. The product's efficacy is apparently based upon the antimicrobial activity of benzalkonium chloride in the formulation. The agency's evaluation of this clinical study is discussed under comment 5 below.

References

(1) OTC Volumes 070078, 070079, 160242, 160247, and 160427.

(2) OTC Volume 020016.

(3) OTC Volume 020051.

(4) Letter from J. H. Lee, EPA, to C. J. Baker, Albright and Wilson, Inc., dated October 30, 1986, in OTC Volume 02DTFM, Docket No. 75N-183D, Dockets Management Branch.

B. Comments on Benzalkonium Chloride.

5. As noted in comment 4 above, two manufacturers submitted information (Refs. 1 and 2) on products containing benzalkonium chloride.

Benzalkonium chloride has been reviewed for safety for topical use in four other OTC drug rulemakings. In the advance notice of proposed rulemaking for OTC topical antimicrobial drug products (September 13, 1974; 39 FR 33103), the Antimicrobial I Panel concluded that this ingredient and two other quaternary ammonium compounds at a concentration of 1:750 (0.13 percent) could be regarded as safe as a skin wound cleanser provided that the product is not used repeatedly, covered with occlusive bandaging, or used in deep or extensive wounds (39 FR 33116). However, the Panel concluded that further toxicity data characterized by the absorption and systemic toxicity in a rodent and nonrodent species should be generated prior to the placement of these quaternary ammonium compounds into Category I for use other than as a skin wound cleanser (39 FR 33132). In the tentative final monograph for OTC topical antimicrobial drug products (January 6, 1978; 43 FR 1210), the agency did not include recommendations for further animal studies and stated that the systemic toxicity of quaternary ammonium compounds in animals is low and is indicative of and reflects the surfactant nature of the molecule (43 FR 1236). The agency stated that even though specific absorption and systemic levels in humans have not been reported for the three quaternary ammonium compounds reviewed, considering the concentrations applied, and extrapolating from animal studies, toxic effects at use levels would be unlikely (43 FR 1237). However, both the Panel (39 FR 33132) and the agency (43 FR 1237) noted that there are many reports on the irritating nature of the quaternary ammonium compounds on the skin, mucous membranes, and the eye and that the degree of irritation increases when quaternary ammonium compounds are used under occlusion.

In the advance notice of proposed rulemaking for OTC oral health care drug products (May 25, 1982; 47 FR 22760), the Advisory Review Panel on OTC Oral Cavity Drug Products (Oral Cavity Panel) concluded that benzalkonium chloride is safe as an OTC antimicrobial agent for topical use on the mucous membranes of the mouth and throat when used at concentrations of 0.01 to 0.02 percent. However, for children under 3 years of age the Panel did not recommend a dosage except under the advice and supervision of a dentist or physician.

In the advance notice of proposed rulemaking for OTC vaginal drug products (October 13, 1983; 48 FR 46694), the Advisory Review Panel on OTC Contraceptives and Other Vaginal Drug Products (Vaginal Panel) concluded that data are insufficient to prove that benzalkonium chloride is safe for the relief of minor vaginal irritations. The Panel noted that toxicologically the quaternaries appear to be relatively safe when used in dilute solution and without occlusive dressing (48 FR 46717 to 46718). However, the Panel expressed concern that the relative ineffectiveness of quaternaries as bactericidal agents raise significant concern as to their safety for use in vaginal products because of the possibility of overgrowth of pathogenic organisms.

Benzalkonium chloride was also reviewed by the Advisory Review Panel on OTC Miscellaneous External Drug Products (Miscellaneous External Panel) in the advance notice of proposed rulemaking for OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis (December 3, 1982; 47 FR 54646). The Panel concluded that benzalkonium chloride is safe for OTC use for controlling dandruff in concentrations of 0.05 to 0.2 percent (47 FR 54671).

Animal safety data for benzalkonium chloride included a 1-year feeding study in dogs (Refs. 3 and 4) and a 12-week feeding study in rats (Refs. 3 and 5). In addition, 2-year rat feeding studies were cited (Refs. 1 and 3). One report (Ref. 6) attempted to calculate the long-term safety factor in humans from use of

eating utensils sanitized with benzalkonium chloride and concluded that there was a rather wide margin of safety of 833 to nearly 7,000 times.

Pfeffer and Smith (Ref. 7) reported a skin test that involved application of a 2-inch square gauze patch moistened with a 1:1,000 dilution of benzalkonium chloride to the backs of 100 infants aged 1 day to 2 years. The patch was left in contact with the skin for 24 hours. No reactions of any kind were noted either at the end of the 24-hour period or after 48 hours. The authors also reported that no irritation was noted in any of the 154 patients on whom benzalkonium chloride-rinsed diapers were used therapeutically or prophylactically (Ref. 7). (These studies are discussed below.)

The manufacturer of the disposable towelettes impregnated with a lotion containing benzalkonium chloride submitted two studies on the finished product to show that it did not irritate the skin. The manufacturer noted that the lotion product was formulated to contain 0.02 percent benzalkonium chloride by weight, but that the amount of ingredient expressed from the paper towelette is 0.015 percent because the balance is irreversibly adsorbed on the paper. In one study (Ref. 8), 100 females were subjected to prophetic patch tests. Towelettes were cut in quarters, folded, and applied to the back and covered with a sheer occlusive patch. This patch was then reinforced with ½-inch-waterproof tape to assure good contact and allow the square perforated area to breathe. The material remained in contact with the skin for 48 hours. Upon removal of the patches, the test areas were observed at once for immediate reaction. A final examination for delayed reactions was made 72 hours after application. Retests were done 14 days later. The reported results were that there was no evidence of any primary irritation on the initial 48-hour patch test and no indication of sensitization of the skin on the retest performed 14 days later. However, the agency notes that because the perforated area of the patch was allowed to breathe, the results may not be reflective of irritation that may develop in an occluded diaper area.

In the second study, a clinical test was conducted for 4 weeks on over 100 infants on which impregnated towelettes were used to cleanse the hands, face, and diaper area (Ref. 9). A consulting dermatologist examined the infants at the start of the study, at week two, and at week four and found no adverse reactions to the use of the tested product.

The agency finds the above studies show that the skin irritation potential of benzalkonium chloride when used under occlusion for a short term does not appear to be a problem. However, the agency is not able to reach any conclusions about the sensitizing potential of the ingredient under the occlusive conditions found in the diaper area when this ingredient is used chronically on infants and children. The agency has determined that additional data are needed to demonstrate the safety of benzalkonium chloride or other quaternary ammonium compounds for use in diaper rash drug products for chronic use on infants and children. Studies need to be done to determine the degree of absorption from broken skin (as evidenced by blood levels) and the relationship between these blood levels and the blood concentration that produces no adverse effect in animals. In addition, studies are needed to determine the skin irritation and sensitization potential in infants when the ingredient is applied chronically under occlusion as occurs in the diaper area.

Several studies involved the antibacterial activity of fabric impregnated with benzalkonium chloride (Refs. 7, 10, and 11). Latlief et al. (Ref. 11) studied the antimicrobial activity of five quaternary ammonium compounds, including benzalkonium chloride, used to impregnate cotton fabric to prevent ammonia formation from urea by *Proteus mirabilis* (*P. mirabilis*). Benzalkonium chloride applied by exposing the fabric for 10 minutes at 45 °C was capable of inhibiting ammonia production for 16 hours at a 1:25,000 dilution, for 24 hours at a 1:3,000 dilution, and up to 7 days at a 1:1,000 dilution. All controls became positive in 10 hours, hence, the 16- and 24-hour readings represent a 6- and 14-hour delay in ammonia production.

Pfeffer and Smith (Ref. 7) conducted in vitro bacteriologic studies on the antibacterial activity of dilutions of benzalkonium chloride against a proteus with known urea-splitting activity and a saline suspension of normal infant stool as the test inoculum. They concluded that a 1:5,000 dilution of a disinfectant solution containing 10 percent benzalkonium chloride would inhibit ammonia formation in the diaper. In the discussion of Cooke's ammonia theory of diaper rash (see comment 2 above), the agency noted that this theory has been questioned by more recent studies. As discussed in comment 2 above, the agency has determined that any claims concerning this ammonia theory need to be justified by clinical studies on infants that include bacteriological studies to correlate a reduction in ammonia-producing bacteria with a clinical improvement in the diaper rash. Therefore, the agency does not find in vitro tests alone to be sufficient to prove effectiveness for products used for ammonia-caused diaper rash.

Pfeffer and Smith (Ref. 7) also conducted two clinical trials to prevent or treat diaper rash. In one study to prevent diaper rash, a group of 90 incontinent nonambulatory infants and children in 4 wards in a state mental institution were evaluated for 3 months. The diapers used were cleaned by commercial laundry methods that were the same for each of the 4 wards, except that benzalkonium chloride was used in the final rinse for the diapers used in 2 wards. Thus, the other two wards served as a control. Examinations of the patients in both test and control groups were made twice weekly, but no significant changes in the existing lesions were noted in either group over the 3-month period.

The treatment study was an uncontrolled study in which 64 infants with diaper rash used diapers impregnated with benzalkonium chloride in a 1:5,000 dilution (1 teaspoonful of 10 percent product diluted in 2 quarts of tap water). The infants' mothers were instructed not to use any other medication, such as antiseptic powders, ointments, or diaper rinses. The results in 62 of the 64 cases were good with the time for clearing depending on the severity of the lesions present. All 19 mild and 25 of the 28 moderate cases cleared within 1 week. Two moderate cases cleared after 2 weeks and one failed to respond. Chronic, severe rashes began to improve within a few days and inflammatory changes were gone within 2 weeks. One severe case did not respond. The authors concluded that benzalkonium-chloride impregnated diapers were effective in curing ammoniacal diaper dermatitis in 62 out of 64 cases and under usual circumstances would be equally effective for the prophylaxis of this condition. However, this was an uncontrolled study, and the agency does not consider it adequate to demonstrate effectiveness.

Kantor, Botwinick, and Botwinick reported a controlled clinical study that evaluated the effectiveness of using disposable towelettes moistened with benzalkonium chloride for diaper rash (Ref. 9). Diaper rash was described as a "Condition of the skin occurring in the groin and buttocks as well as in the folds, associated with wetness, warmth, and friction rather than caused by the diaper material itself. It is manifested by redness, pustules, erosion, etc." During the 4-week study, the incidence of

diaper rash was noted at the start of the study and at 2 and 4 weeks. A group of 102 infants was treated with the benzalkonium chloride towelettes in addition to their usual cleansing regimen; 25 percent improved, 64 percent remained the same, and 11 percent became worse. Of the control group of 98 infants who used their usual cleansing regimen only, 18 percent improved, 56 percent stayed the same, and 26 percent became worse. The authors concluded that the treated group was significantly better than the control group and that the treated group had a less dry or scaly diaper area than the control group. However, the agency notes that this study was not adequately controlled. For example, instead of comparing the benzalkonium-chloride impregnated disposable towelettes with disposable towelettes moistened only with the (alcohol) vehicle as the control, the control group was not provided any sort of disposable towelettes but was instructed to follow its individual cleansing regimen. Thus, the cleansing regimen was not comparable between the treatment and control groups. These groups also differed in other ways, e.g., the number that used cloth diapers or disposable diapers and the number of diapers used daily. Finally, bacteriological studies were not done on the infants. Therefore, while this study indicates that benzalkonium chloride may be beneficial for treating diaper rash, additional data from properly controlled studies are needed before this ingredient can be classified as Category I for effectiveness. The agency believes that in vivo bacteriological studies are needed; specifically in vivo studies in infants to demonstrate the effect of the antibacterial activity of benzalkonium chloride on the skin flora and whether this effect correlates with clinical improvements in the diaper rash. Also bacteriological studies are needed to show that the long-term use of benzalkonium chloride does not result in potentially harmful changes in the normal flora of the skin in the diaper area. Based upon the above discussion, the agency is classifying benzalkonium chloride for use in diaper rash drug products in Category III for both safety and effectiveness.

References

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(2) OTC Volume 020051.

(3) Coulston, F., et al., "Toxicology of Benzalkonium Chloride Given Orally in Milk or Water to Rats and Dogs," *Toxicology and Applied Pharmacology*, 3:584–594, 1961.

(4) Coulston, F., and P. Garvin, "TS–19, Roccal, Germicide, One-Year Chronic Toxicity in Dogs: A Comparison of the Toxicity of Roccal in Combination with Milk and with Water," unpublished report in OTC Volume 020016.

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(6) Drobeck, H.P., "Evaluation of Safety Factor for Roccal Residue on Eating Utensils," unpublished report in OTC Volume 020016.

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(8) Blau, S., and N. Kanof, "Sample #7775 Washkins for Babies," unpublished report in OTC Volume 020051.

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C. Comment on Benzethonium Chloride

6. One manufacturer submitted data (Ref. 1) to the Miscellaneous External Panel for a diaper rash cream product containing a combination of benzethonium chloride, talc, dl-methionine, cysteine hydrochloride, and protein hydrolysate containing the amino acids 1-leucine, 1-isoleucine, 1-methionine, 1-phenylalanine, and 1-tyrosine. The labeling states that the product is for the treatment of, and as an aid in the prevention of, diaper rash, cradle cap, excoriations and chafing of the infant skin and that it "contains a germicide to help prevent irritation." The submission included studies on the use of the finished product in the treatment of ammonia dermatitis (diaper rash) and in vitro data on benzethonium chloride in prevention of ammonia formation from urea by *P. mirabilis*.

Elsewhere in this issue of the **Federal Register**, the agency states its tentative conclusions on the use of skin protectant ingredients for the treatment and prevention of diaper rash. The ingredients referred to by the comment, with the exception of benzethonium chloride, are addressed in that rulemaking. The use of benzethonium chloride in the treatment or prevention of diaper rash is addressed here.

Benzethonium chloride has been reviewed for safety for topical use in five other OTC drug rulemakings. In the advance notice of proposed rulemaking for OTC topical antimicrobial drug products (September 13, 1974; 39 FR 33103), the Antimicrobial I Panel concluded that this ingredient and two other quaternary ammonium compounds at a concentration not greater than 1:750 (0.13 percent) could be regarded as safe as a skin wound cleanser provided that the product is not used repeatedly, covered with occlusive bandaging, or used in deep or extensive wounds (39 FR 33116). However, that Panel concluded that further toxicity data, characterized by the absorption and systemic toxicity in a rodent and nonrodent species, should be generated prior to the placement of these quaternary ammonium compounds into Category I for use other than as a skin wound cleanser (39 FR 33132). In the tentative final monograph for OTC topical antimicrobial drug products (January 6, 1978; 43 FR 1210), the agency did not include recommendations for further animal studies and stated that the systemic toxicity of quaternary ammonium compounds in animals is low and is indicative of and reflects the surfactant nature of the molecule (43 FR 1236). The agency stated that even though specific absorption and systemic levels in humans have not been reported for the three quaternary ammonium compounds reviewed, considering the concentrations applied, and extrapolating from animal studies, toxic effects at use levels would be unlikely (43 FR 1237). However, both the Panel (39 FR 33132) and the agency (43 FR 1237) noted that there are many reports on the irritating nature of the quaternary ammonium compounds on the skin, mucous membranes, and the eye and that the degree of irritation increases when quaternary ammonium compounds are used under occlusion.

In the advance notice of proposed rulemaking for OTC antifungal drug products (March 23, 1982; 47 FR 12480), the Antimicrobial II Panel concluded that there are insufficient data available to permit final classification of the safety of benzethonium chloride for use in the treatment of athletes foot, jock itch, and ringworm. The Panel reviewed safety data in animals but noted that absorption from broken skin is unknown. The Panel recommended that studies be done to determine the degree of absorption of benzethonium chloride from broken skin, as evidenced by blood levels, and the relationship between these blood levels and the blood levels that produced no adverse effects in animals (47 FR 12527).

In the advance notice of proposed rulemaking for OTC oral health care

drug products (May 25, 1982; 47 FR 22760), the Oral Cavity Panel expressed concern about the safety of benzethonium chloride for long-term use on a daily basis in mouth rinses or gargles (47 FR 22860). The Panel was concerned that, although the salts of quaternary nitrogenous compounds are normally not lipophilic and not ionized, and are, therefore, poorly absorbed through the mucous membranes, the introduction of a highly lipophilic radical into the structure of benzethonium chloride might increase the lipid solubility and thus enhance penetration of this compound through the mucous membranes. The Panel feared that this would increase systemic absorption and therefore increase the possibility that toxic doses could be absorbed through the mucous membranes of the mouth and throat. The Panel stated that adequate data on absorption and attainment of toxic blood levels and the metabolic fate of the quaternary ammonia compounds are not available. It also stated that data on cumulative effects, including mutagenic, tumorigenic, or teratogenic effects, from continued daily use over a prolonged period of time in a mouthwash or gargle are not available. The agency finds that the use of benzethonium chloride on the mucous membranes in the diaper area for an extended period of time raises similar concerns.

In the advance notice of proposed rulemaking for OTC vaginal drug products (October 13, 1983; 48 FR 46694), the Vaginal Panel concluded that data are insufficient to prove that benzethonium chloride is safe for the relief of minor vaginal irritations. The Panel noted that toxicologically the quaternaries appear to be relatively safe when used in dilute solution and without occlusive dressing (48 FR 46717 to 46718). However, the Panel added that the relative ineffectiveness of quaternaries as bactericidal agents raises significant concern as to their safety for use in vaginal products because of the possibility of overgrowth of pathogenic organisms.

OTC topical use of benzethonium chloride for controlling cradle cap was reviewed by the Miscellaneous External Panel in the advance notice of proposed rulemaking for OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis (December 3, 1982; 47 FR 54646). That Panel evaluated the same submission as identified above (Ref. 1). Although no data were submitted on the product's use in the control of cradle cap, the Panel concluded that the data related to the product's use in treating diaper rash showed that no irritation or sensitization was observed in any of the infants (Ref. 2). The Panel also noted that, as a preliminary to the study, the finished product was applied to the arms and forearms of 25 children and 25 infants for up to 4 hours in some cases. No irritation or other side effects were noted. The Panel concluded that benzethonium chloride is safe for OTC use in controlling cradle cap (47 FR 54671).

Although one panel has recommended that benzethonium chloride is safe for use in treating cradle cap, it does not necessarily follow that the ingredient is also safe for treating diaper rash. Other panels have raised concern about repeated use and use under an occlusive dressing. When used for treating and/or preventing diaper rash, the product is likely to be used for a long period of time, possibly over a large area and on more sensitive skin, and will be used under occlusion, i.e., diapers. The agency notes that, in the irritation test by Susca and Geuting (Ref. 2), the authors do not state whether or not occlusion was used to maintain the product in close contact with the skin. Therefore, the agency is not able to reach any conclusions about the sensitizing potential of the ingredient under the occlusive conditions found in the diaper area when this ingredient is used chronically on infants and children. The agency has determined that additional data are needed to demonstrate the safety of benzethonium chloride or other quaternary ammonium compounds for use in diaper rash drug products for chronic use on infants and children. Studies need to be done to determine the degree of absorption from broken skin (as evidenced by blood levels) and the relationship between these blood levels and the blood concentration that produces no adverse effect in animals. In addition, studies are needed to determine the skin irritation and sensitization potential in infants when the ingredient is applied chronically under occlusion as occurs in the diaper area.

Two clinical studies (Refs. 2 and 3) were conducted on the finished product compared with a placebo cream with no active ingredients. Because the finished product used in the studies contained other active ingredients in addition to benzethonium chloride, the contribution of benzethonium chloride alone cannot be determined. Also, both studies lacked sufficient details to be considered adequately controlled clinical trials. (For a discussion of these studies, see the agency s conclusions on the use of skin protectant drugs for diaper rash, elsewhere in this issue of the **Federal Register**.)

The submission included articles from the literature to demonstrate effectiveness (Refs. 4 and 5) and a report by Latlief et al. (Ref. 6) on the antimicrobial activity of five quaternary ammonium compounds, including benzethonium chloride, used to impregnate cotton fabric to prevent ammonia formation from urea by *P. mirabilis*. In the discussion of Cooke's ammonia theory on diaper rash (see comment 2 above), the agency noted that this theory has been questioned by more recent studies. As discussed in comment 2 above, any claims concerning this ammonia theory need to be justified by clinical studies on infants that include bacteriological studies to correlate a reduction in ammonia-producing bacteria with a clinical improvement in the diaper rash. Therefore, the agency does not find in vitro tests alone to be sufficient to prove effectiveness for ammonia-caused diaper rash.

The agency believes that in vivo bacteriological studies are needed; specifically in vivo studies in infants to demonstrate the effect of the antibacterial activity of benzethonium chloride on the skin flora and whether this effect correlates with clinical improvements in the diaper rash. Also bacteriological studies are needed to show that the long-term use of benzethonium chloride does not result in potentially harmful changes in the normal flora of the skin in the diaper area.

Based upon the above discussion, the agency is classifying benzethonium chloride for use in diaper rash drug products in Category III for both safety and effectiveness.

References

(1) OTC Volume 160042.

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(3) Christian, J.R., and F. Gonzalez, "Topical Treatment of Acute and Chronic Diaper Rash with Amino Acid Creme," *Clinical Medicine*, 8:225–231, 1961.

(4) Lawrence, C.A., "Quaternary Ammonium Surface-Active Disinfectants," in "Disinfection, Sterilization and Preservation," edited by C.A. Lawrence and S.S. Block, Lea and Febiger Publishing Co., Philadelphia, pp. 430–452, 1968.

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(6) Latlief, M.A., et al., "Bacteriostatic, Germicidal, and Sanitizing Action of Quaternary Ammonium Compounds on Textiles: Prevention of Ammonia Formation from Urea by *Proteus mirabilis*," *The Journal of Pediatrics*, 39:730–737, 1951.

D. Comment on Boric Acid

7. One comment noted that boric acid and other borates were used in OTC topical antimicrobial drug products for the treatment of diaper rash, and that boric acid was listed as an ingredient in marketed products submitted to the Panel (47 FR 39408). The comment stated that its review of the OTC volumes cited at 47 FR 39409 showed that boric acid was an ingredient in two diaper rash powder products, one ointment, and one cream at concentrations ranging from 0.5 to 7.5 percent, and that the boric acid was used as a buffer to react with ammonia. The comment also referred to its comments to the other rulemakings (external analgesic, antifungal, and skin protectant) for diaper rash drug products.

The agency has reviewed the references referred to by the comment (Refs. 1 through 4) and notes that the products contain boric acid at concentrations of 0.5, 3, 4.55, and 7.14 percent. However, the product containing 0.5 percent did not have a labeling claim for diaper rash. Although the comment stated that boric acid was used as a buffer to react with ammonia, which implies that it was an inactive ingredient, the labeling of two products (Refs. 1 and 2), and information in the data submitted for the third product (Ref. 4) list boric acid as an active ingredient.

In evaluating the current formulations of these products, the agency has determined that the three products with diaper rash claims have been reformulated to delete the boric acid (Refs. 5, 6, and 7). The agency has surveyed products currently available in the marketplace and identified one additional ointment that contains 5 percent boric acid and is labeled for use in diaper rash (Ref. 8). The manufacturer has not submitted any data on this product to the OTC drug review.

The Miscellaneous External Panel stated that antimicrobial products to control bacteria may prevent further skin irritation associated with diaper rash (47 FR 39406 at 39409). The Panel did not review or categorize ingredients for use in diaper rash drug products, but recommended that those ingredients be referred to appropriate rulemakings. Although boric acid was not classified by the Antimicrobial I Panel, the Antimicrobial II Panel classified it in Category II for acne use and in Category III for antifungal use in athletes foot, jock itch, and ringworm. The Antimicrobial II Panel said it was safe at concentrations of 5 percent or less, but there were no data available to evaluate the effectiveness of boric acid for acne and antifungal uses.

A number of other OTC advisory review panels have evaluated the safety of boric acid and have found it to be unsafe for use in OTC anorectal, skin protectant, dandruff and seborrheic dermatitis, oral health care, and vaginal (at greater than 1 percent concentration) drug products. Therefore, based on these panels' recommendations and the available data, the agency considers boric acid to be Category II for safety as a topical antimicrobial active ingredient in diaper rash drug products.

The comments to the other rulemakings for OTC diaper rash drug products requested that boric acid be considered as an inactive ingredient in those products. These comments are addressed elsewhere in this issue of the **Federal Register**.

References

(1) OTC Volume 160040.
(2) OTC Volume 160077.
(3) OTC Volume 160091.
(4) OTC Volume 160236.
(5) Comment No. RPT005, Docket No. 75N–0183, Dockets Management Branch.
(6) Letter from J.A. Devaney, The Mentholatum Company, Inc., to L. Geismar, FDA, dated October 23, 1986, in OTC Volume 02DTFM, Docket No. 75N–183D, Dockets Management Branch.
(7) Comment Nos. C00163 and LET083, Docket No. 75N–0183, Dockets Management Branch.
(8) Smith, G.H., "Diaper Rash and Prickly Heat Products," *in* "Handbook of Nonprescription Drugs," 8th Ed., American Pharmaceutical Association, Washington, p. 651, 1986.

E. Comment on Calcium Undecylenate

8. One manufacturer submitted data for two diaper rash products (an ointment and a powder) containing 15 percent calcium undecylenate to the Miscellaneous External Panel (Ref. 1) and the Antimicrobial I Panel (Ref. 2). The information submitted indicated that the powder product also contained 3 percent boric acid as an active ingredient. A subsequent submission by the same manufacturer (Ref. 3) stated that both products had been reformulated, i.e., the boric acid was deleted from the powder product and the calcium undecylenate was deleted from the ointment product. Thus, the ointment product no longer contains an antimicrobial active ingredient. The current labeling (Ref. 4) for the reformulated baby powder product, which now contains 10 percent calcium undecylenate in talc (Ref. 3), in part reads "helps heal, relieve, and prevent diaper rash, prickly heat, and chafing," and "medicated with calcium undecylenate to kill harmful bacteria and fungi while forming a protective barrier that repels moisture and helps keep sensitive skin dry."

Calcium undecylenate is discussed for its antibacterial claims in this document and for its antifungal claims in the document on OTC antifungal diaper rash drug products, published elsewhere in this issue of the **Federal Register**. Talc and skin protectant claims are discussed in the document on OTC skin protectant diaper rash drug products, published elsewhere in this issue of the **Federal Register**. Boric acid is discussed in comment 7 above.

Undecylenic acid and its salts (for a total undecylenate concentration of 10 to 25 percent) were recommended as Category I ingredients for use in the treatment of athlete's foot, jock itch, and ringworm by the Antimicrobial (II) Panel (March 23, 1982; 47 FR 12480). That Panel recommended the following warning for all OTC antifungal ingredients: "Do not use on children under 2 years of age except under the advice and supervision of a doctor." That Panel was also concerned about the use of any antifungal agent indefinitely in the groin, because the groin is a sensitive area, and recommended labeling to limit products used for jock itch to 2 weeks only (47 FR 12490).

The Panel noted that undecylenic acid, an unsaturated fatty acid, is a normal constituent of human sweat (47 FR 12509). Fatty acids were first chosen 50 years ago for evaluation as topical therapeutic agents because they are found in sweat and therefore represent a more physiological method of treatment than the usual toxic antiseptic chemicals which may be more irritating (Ref. 6).

Based on the above Panel review and information, it appears that there may be no systemic toxicity hazard from topical absorption of calcium undecylenate. Nevertheless, the agency concludes that the submitted data are not sufficient to establish safety for topical OTC use for diaper rash in infants. Although the clinical studies in the submissions (Refs. 1 and 2) that are discussed below for efficacy suggest that a concentration of up to 15 percent calcium undecylenate would not be irritating for use on infants with diaper rash, they did not include specific tests for irritation or sensitizing potential such as patch-testing. The agency concludes that before calcium undecylenate can be considered safe for

OTC use in diaper rash drug products, studies are needed to determine the skin irritation and sensitization potential in infants when this ingredient is applied chronically under occlusion as occurs in the diaper area.

As part of the agency's Drug Efficacy Study Implementation (DESI) program, the National Academy of Sciences-National Research Council (NAS–NRC) Panel on Drugs Used in Dermatology II evaluated the ointment containing 15 percent calcium undecylenate and the powder containing 15 percent calcium decylenate and 3 percent boric acid and concluded that the ointment was effective for the treatment of diaper rash, chafing, minor skin irritations, and prickly heat, and that the powder product was effective for the prevention and treatment of diaper rash, prickly heat, chafing, and minor skin irritations and for the prevention and treatment of irritation due to incontinence" (Ref. 7). Reports by Litter (Ref. 8) and Sezar and Keitel (Ref. 9) were cited as supporting documentation. Subsequently, in the **Federal Register** of September 17, 1971 (36 FR 18599 to 18600), the agency stated its position on the NAS–NRC report and classified the above label claims as "possibly effective." Agency action regarding these products under the DESI program was subsequently deferred to the OTC drug review (January 11, 1974; 39 FR 1580).

In response to an agency request, additional studies, both published and unpublished, were submitted (Ref. 3) specifically to demonstrate the antibacterial and antifungal activity of undecylenic acid and its salts for use on diaper rash. In vitro studies using 5, 10, and 15 percent calcium undecylenate demonstrated significant zones of inhibition of *S. aureus, Staphylococcus epidermidis, E. Coli,* and *Pseudomonas aeruginosa* (*P. aeruginosa*).

The submissions to the advisory review panels (Refs. 1 and 2) included summaries of clinical studies and related case histories describing the use of a powder product containing 5 percent boric acid and 15 percent calcium undecylenate on infants with diaper dermatitis. The submissions reported that successful therapeutic results were obtained in most cases. In the in vivo study by Litter (Ref. 8), 200 infants and children aged 1 month to 5 years with various skin lesions, which included diaper rash, were studied. One hundred of the infants were treated with a 15-percent calcium undecylenate/3 percent boric acid product in a neutralized talc base and the remaining infants were treated with cornstarch or a bland baby powder and served as the control group. Cultures from the 100-treated infants were taken and examined. Bacteria were cultured in 38 of the treated cases, although the bacteria were not identified. Of the 38 cases in which bacteria were cultured, treatment with the powder product resulted in improvement rated as excellent in 16 cases, moderate in 18 cases, and slight in 4 cases. Litter reported that the skin irritations in the control group lasted 2 to 3 times longer than in the treatment group; however, the base in the control product was not the same as that in the treatment product.

One large-scale clinical investigation (Ref. 10), conducted in a hospital for a three-month period, involved 282 infants admitted with clear skin who were given daily prophylactic diaper care and after bath care which included a powder product. A powder containing 5 percent boric acid and 15 percent calcium undecylenate was applied to 168 infants; 21 of these infants (12.5 percent) developed rashes during the course of the study. A powder containing only 5 percent boric acid was applied to a control group of 114 infants; 24 of these infants (21 percent) developed rashes. The manufacturer contended that these results showed a reduction of 68 percent in the incidence of diaper rash in the calcium undecylenate group as compared to the control group.

Another study, by Robinson (Ref. 11), included 143 infants, ranging in age from 2 weeks to 23 months, selected at random from patients attending a well-baby clinic. Seventy-three of these infants had no evidence of a skin eruption. Contact dermatitis of the diaper area was present in 26 infants, and intertriginous eruptions, noncontact in origin, were present in 44 infants. The product used was a powder containing 15 percent calcium undecylenate, 3 percent borax acid, and 81.75 percent talcum. However, no placebo product was used. Mothers were instructed to apply the powder lightly, without rubbing, to the diaper area each time the diapers were changed. The infants were bathed with a mild soap and thoroughly rinsed. Diapers were washed in mild soap flakes and rinsed 3 times with warm clear water. Baby oils, creams, and lotions were not used. The infants were cleansed with clear water or mineral oil following bowel movements. Use of plastic or rubber pants was discouraged. Of the 70 infants with diaper rash or intertriginous eruptions, 60 were definitely improved, 8 remained unchanged, and 2 developed evidence of local irritation, which subsided when the powder was discontinued. Sixty-nine of the infants with no skin eruptions did not develop any eruptions; 4 of these infants had irritation. The institution of the cleanliness regimen was considered to be a major factor in producing the high percentage of satisfactory results. Robinson concluded that the powder is of value in mild diaper rash in infants. Also, because of its low sensitizing potential, the author stated that it is superior to baby powders containing various antiseptics which have irritating properties.

None of the submitted studies concerned the use of a product which used calcium undecylenate as the sole antimicrobial active ingredient. In addition, the studies described a powder product containing 15 percent calcium undecylenate. The currently marketed product contains only 10 percent calcium undecylenate, and there are no clinical effectiveness studies to support this concentration. Therefore, none of the data submitted provides sufficient evidence to establish the effectiveness of 10 percent calcium undecylenate for diaper rash use.

The agency is also concerned about the effect of calcium undecylenate on the skin flora under the occlusive conditions found in the diaper area when this ingredient is used chronically on infants and children. The agency believes that further in vivo bacteriological studies are needed, specifically in infants, to demonstrate the effect of the antibacterial activity of calcium undecylenate on the skin flora and whether this correlates with clinical improvements in diaper rash, and further whether long-term use of calcium undecylenate results in potentially harmful changes in the normal flora of the skin in the diaper area.

Accordingly, the agency is classifying calcium undecylenate for use in diaper rash drug products for antibacterial claims in Category III for both safety and effectiveness.

References

(1) OTC Volumes 160236.

(2) OTC Volumes 070021.

(3) Comment No. RPT005, Docket No. 75N-0183, Dockets Management Branch.

(4) Letter from J.L. Miller, Pennwalt Corporation, Pharmaceutical Division, to L. Geismar, FDA, dated December 28, 1987, in OTC Volume 02DTFM, Docket No. 75N-183D, Dockets Management Branch.

(5) OTC Volume 070029.

(6) Peck, S.M., and H. Rosenfeld, "The Effects of Hydrogen Ion Concentration, Fatty Acids, and Vitamin C on the Growth of Fungi," *The Journal of Investigative Dermatology*, 1:237–265, 1938.

(7) Rostenberg, A., "Caldesene," National Academy of Sciences—National Research

Council, Drug Efficacy Study, NDA 8967, Log 602.

(8) Litter, L., "Topical Therapy and Prophylaxis in Dermatoses of Infancy and Childhood," *Connecticut State Medical Journal*, 21:1045–1046, 1957.

(9) Sezar, V., and H. Keitel, "Studies in Neonatal Diaper Dermatitis: II. Use of a Powder Containing Undecylenate," *The Turkish Journal of Pediatrics*, 6:160–162, 1964.

(10) Vignec, A.J., "Report on Prophylactic and Therapeutic Use of Desenex Baby Powder for a Three-Month Period Ending November 1," pp. 83–116, in OTC Volume 160236.

(11) Robinson, H.M., Jr., "A Study of a Protective Powder," *Southern Medical Journal*, 52:1421–1422, 1959.

F. Comment on Chloroxylenol

9. A submission to the Miscellaneous External Panel (Ref. 1) requested Category I status for a product containing 0.5 percent chloroxylenol (parachlorometaxylenol) in combination with 0.2 percent aluminum dihydroxy allantoinate and 45 percent microporous cellulose for the prevention of diaper rash. The submission included general safety data and in vitro antimicrobial effectiveness data on chloroxylenol and the combination product. Another submission (Ref. 2), which was made to the Antimicrobial I Panel, included data on a 5-percent chloroxylenol solution used at various dilutions as a diaper soak and as a solution applied directly to the skin to prevent and treat diaper rash.

The agency has reviewed the safety of chloroxylenol in the rulemakings for OTC topical antimicrobial drug products (43 FR 1210 at 1222 and 1238) and OTC antifungal drug products (54 FR 51136 at 51139). In the antifungal rulemaking, the agency proposed that chloroxylenol is safe for short-term use on small areas of the body. However, this finding is not considered adequate for a diaper rash drug product which should be shown safe for long-term use over large areas of the body.

The Antimicrobial I Panel, noting that only the most superficial toxicity data in animals was submitted for its review, placed chloroxylenol in Category III for all antiseptic uses (39 FR 33103 at 33134). The Panel stated its view that toxicity in rodent and non-rodent species, substantivity, blood levels, distribution and metabolism as well as any systemic absorption studies must be characterized before the ingredient could be considered for placement in Category I. The Panel was particularly concerned about the safety of using chloroxylenol in infants and recommended the warning: "not to be used on infants under six months of age." The Panel noted that chloroxylenol is metabolized by glucuronide and sulfate conjugation and there is a reported deficiency of metabolic conjugating mechanisms in infants. The Panel recommended that a toxicological evaluation of chloroxylenol should include studies to demonstrate safety in animals deficient in these detoxification mechanisms. The Panel stated that the effect of impaired liver function on elimination and toxicity would be important because the liver is considered a major organ for conjugation (39 FR 33134).

In the tentative final monograph for OTC topical antimicrobial drug products (43 FR 1210), the agency affirmed the conclusions of the Antimicrobial I Panel that chloroxylenol should not be used on infants until additional safety studies are conducted. The agency also proposed a warning not to use chloroxylenol-containing products on infants under 6 months of age unless such studies are conducted (43 FR 1238). As discussed in comment 3 above, the agency believes a diaper rash drug product should be safe for use on infants of all ages. Therefore, the agency does not consider a warning not to use a diaper rash drug product containing chloroxylenol on infants under 6 months of age adequate to support safe OTC use. Appropriate studies need to be conducted to demonstrate that chloroxylenol in a diaper rash drug product can be considered safe for use on infants of all ages.

The Antimicrobial II Panel categorized chloroxylenol (0.5 to 3.75 percent) as safe (Category I) for short-term use (up to 13 weeks) in OTC antifungal drug products. The Panel was concerned about the effect of chronic administration of chloroxylenol on the liver, but did not consider that topical application of chloroxylenol to small areas of the skin over short periods of time would result in liver damage (47 FR 12534 to 12535). In the tentative final monograph for OTC antifungal drug products (54 FR 51136 at 51139), the agency affirmed the conclusions of the Antimicrobial II panel to limit the use of chloroxylenol to 13 weeks because possible liver effects may become significant with long-term (repeated/daily) exposure times. The agency has determined that additional data characterizing the level of absorption, metabolism, and excretion following topical administration are needed to assess the safety of the chronic topical use of chloroxylenol (Ref. 3).

Data were submitted to the rulemaking for OTC topical antifungal drug products (Refs. 4 through 7) in response to agency concerns about the sensitization and irritation potential of chloroxylenol (Ref. 8). The data, submitted for an OTC topical antifungal drug product containing 2 percent chloroxylenol, consist of primary skin and eye irritation in rabbits (Refs. 4 and 5), a repeated insult patch test to the groin of ten adults (Ref. 6), and a clinical study of the effectiveness of the product (Ref. 7). In the tentative final monograph for OTC antifungal drug products, after reviewing the submitted data, the agency concluded that 2 percent chloroxylenol does not appear to have a potential for sensitization or irritation (54 FR 51136 at 51139). While the agency considers the studies supportive of the lack of irritation or sensitization potential for the ingredient, they are not adequate to demonstrate the lack of such potential when the ingredient is applied chronically under occlusion as occurs in the diaper area.

Chloroxylenol is a chlorinated phenol and has been shown to have a low level toxicity compared with other chlorinated phenolic compounds (Ref. 9). Phenol (see comment 16 below) and other phenol derivatives, such as hexachlorophene (see comment 10 below) and resorcinol (see comment 17 below), have also caused severe systemic toxicity, including death, in infants when applied externally, even in relatively low dilutions. Accordingly, the agency believes particular caution is needed when considering the topical use of any phenolic compound on infants.

Green and Preece (Ref. 10) conducted a study in rats on the toxic effects of maximal body exposure of chloroxylenol. In this study, rats were shaved and immersed for 30 minutes with only the head protruding in baths containing various dilutions of a chloroxylenol containing antiseptic. When immersed, the rats struggled, became comatose, and, particularly for the higher concentrations, lost consciousness and died during or after immersion. There was severe reddening externally and internally in the affected animals with the skin irritation resembling scalding. With 10 adult rats, which were observed for 7 days, of 8 deaths, 5 occurred within 2 hours, 2 more within 24 hours, and 1 more within 48 hours after exposure to a 3.2 or 5.14 percent antiseptic formulation. With 10 infant rats, which were observed for 24 hours, all 9 deaths occurred within 1 hour after exposure to a 4.95 or 7.86 percent antiseptic formulation. The authors stated that there was no evidence that infant rats were more susceptible than adult rats. Because the antiseptic preparation also contained terpineol and isopropyl alcohol in the vehicle base, it could not be determined which ingredients caused the deaths.

Therefore, Preece (Ref. 11) conducted a similar follow-up study in adult rats using the vehicle base only (no chloroxylenol). The same effects of reddening of the skin with unconsciousness and death occurred. The skin irritation was similar but less severe than that which occurred with the complete formulation. The difference in the results was that the vehicle base caused deaths at concentrations of 12.5 and 20 percent, while the product containing the chloroxylenol caused deaths at 3.2 and 5.14 percent concentration. Therefore, it has been shown that the chloroxylenol contributed to the toxicity of the complete antiseptic formulation.

The agency does not find this study adequate to determine the toxicity of chloroxylenol because the chloroxylenol was not tested alone but in combination with other toxic ingredients. Nevertheless, the study does raise questions concerning the safety of chloroxylenol, particularly regarding possible skin irritation or systemic absorption, when used over large areas of the body.

The agency received one study that included data on the distribution and metabolism of chloroxylenol in rats with a deficient glucuronidation mechanism (Ref. 12). In an effort to determine the contribution of the systemic toxicity of chloroxylenol to the toxicity observed in the above immersion study (Ref. 10), Havler and Rance studied the distribution and metabolism of ^{14}C-chloroxylenol in Sprague-Dawley and UDP-glucuronyl transferase deficient Gunn-Wistar rats after the intravenous, intramuscular, subcutaneous, and oral administration of the labeled ingredient in solution and in a marketed antiseptic. The authors concluded that the study's failure to approach the brain levels of the free phenol found in the immersion studies made it impossible to estimate the contribution of the systemic toxicity of chloroxylenol in the immersion study. They further reported that there was no significant difference between the two strains of rats with respect to the plasma and brain levels of free chloroxylenol attained in the study and that this similarity was further confirmed by the excretion route and metabolic excretion products. They concluded that the metabolic profiles for both strains of rats had been shown to be similar even though the Gunn-Wistar rat is incapable of performing many conjugation reactions due to a deficiency in UDP-glucuronyl transferase activity and that both strains of rats rapidly metabolized the ingredient largely as the glucuronide conjugate.

The data presented by the study are not sufficient to support the authors' conclusions. The study contains no actual data; it contains only summary material that is incomplete. The number of animals studied, gender, and age of the animals are not specified in the study, and the assay method used in the study is insensitive. Moreover, use of the Gunn-Wistar rat model is questionable because both stains conjugated the ingredient to the glucuronide to virtually the same extent, which suggests that the study was compromised either by method or strain. The study also does not address the effect of topical absorption through normal or irritated skin because the study was not conducted using topical administration. Therefore, the study is not considered adequate to demonstrate the safety of using chloroxylenol on infants under 6 months of age. Additional data from studies involving the topical administration of the ingredient to a large surface area of animals deficient in metabolic conjugating mechanisms (such as immature rats or neonate monkeys) are needed to demonstrate the safety of chloroxylenol for use in diaper rash drug products. In these studies, the chloroxylenol and metabolite levels should be determined by state of-the-art analytical techniques, with the single-dose and steady-state pharmacokinetics and tissue distribution determined over at least a four-hour period.

The agency has determined that studies need to be done to determine the degree of absorption from broken skin and from intact skin (as evidenced by blood levels) and the relationship between these blood levels and the blood concentration that produces no adverse effect in animals. In addition, studies are needed to determine the skin irritation and sensitization potential in infants when the ingredient is applied chronically under occlusion as occurs in the diaper area.

In conclusion, the agency has not been presented with sufficient safety data to classify chloroxylenol in Category I for use in diaper rash drug products. Such products are used on a relatively large area of the infant's body, are used under occlusion, and may be used for prolonged periods of time. The following types of data are needed to show that chloroxylenol is safe under such conditions of use:

(1) Studies in animals deficient in metabolic conjugating mechanisms (such as immature rats or neonate monkeys) to assess the metabolism, distribution, and elimination of chloroxylenol in infants under 6 months of age,

(2) Absorption studies of chloroxylenol applied to small and large areas of broken skin and intact skin as evidenced by blood levels and the relationship between these blood levels and the levels that produce no adverse reactions in animals,

(3) Local effects on sensitizing and irritation potential, and

(4) Potential for hypersensitivity in infants as can occur with other phenolic compounds.

Regarding efficacy, Joseph (Ref. 13) evaluated a solution containing 5 percent chloroxylenol and 10 percent terpineol along with a soap prepared from castor oil and oleic acid by saponification with potassium hydroxide in a 20-percent solution of alcohol in water. Dilutions of this 5 percent chloroxylenol solution were found to be more active than similar dilutions of methylbenzethonium chloride for in vitro activity against urea-splitting bacteria such as *B. ammoniagenes, Proteus vulgaris (P. vulgaris),* and *P. mirabilis.* Joseph stated the the chloroxylenol solution has high antibacterial action against the above bacteria up to a dilution of 1:6,000 and was not inactivated by the presence of foreign protein. Joseph demonstrated that residual germicidal action remained in diapers laundered with a final rinse containing 2 tablespoonfuls of the above 5 percent chloroxylenol solution per gallon of water. Joseph also reported on the use of chloroxylenol solution in the relief and prevention of ammonia dermatitis. Twelve children (age 6 to 18 months) with diaper rash were treated by direct skin application of a dilute chloroxylenol solution (1:100) three times a day until improvement was noticed; then the solution was applied twice a day. All cases cleared after 5 days. After the rash cleared, direct skin application was stopped, and the chloroxylenol solution was used on laundered diapers as a final rinse to impregnate the diapers. After 3 weeks, all children showed a reduction in the incidence and severity of diaper rash and 9 of the cases had cleared. In three severe cases, there was improvement after 3 weeks of using chloroxylenol impregnated diapers but the rash did not clear. Joseph does not explain why the same children with severe diaper rash that cleared after 5 days of direct skin application did not show clearing of the rash after a subsequent 3 weeks of use of impregnated of diapers. This study suffers from an inadequate definition of diaper rash and no definition of

parameters for improvement. In addition, this study was a total formulation study. It does not show the contribution of the chloroxylenol to the product and no control formulation was used. The study also does not include microbiological culture to clarify whether the use of chloroxylenol results in potentially harmful changes in the normal flora of the skin in the diaper area. Therefore, the agency does not find these data adequate to demonstrate the effectiveness of chloroxylenol for diaper rash claims. Based upon the above discussion, the agency is classifying chloroxylenol for use in diaper rash drug products in Category III for both safety and effectiveness.

Regarding the combination product containing chloroxylenol, aluminum dihydroxy allantoinate, and microporous cellulose, the agency notes that the product no longer contains chloroxylenol or aluminum dihydroxy allantoinate (Ref. 14). At this time, any combination product containing chloroxylenol labeled with diaper rash claims is considered Category III.

References

(1) OTC Volume 160357.

(2) OTC Volume 020030.

(3) Letter from W. E. Gilbertson, FDA, to M. K. Bruch, Dexide, Inc., coded LET098, Docket No. 75N–0183, Dockets Management Branch.

(4) Fanaras, J. C., and M. Schmidt, "Primary Skin Irritation Evaluation of Absorbine Athlete's Foot Product (L) 2119A," unpublished study in Comment No. LET010, Docket No. 80N–0476, Dockets Management Branch.

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G. Comments on Hexachlorophene

10. Several submissions to the Antimicrobial I Panel (Ref. 1) and comments to the antimicrobial I rulemaking (Ref. 2) claimed hexachlorophene was safe and effective for use on infants for such claims as total body bathing to prevent staphylococcal infections and to treat or prevent diaper rash. Some of the submissions objected to the agency's proposed statement of policy (January 7, 1972; 37 FR 219) and final rule (September 27, 1972; 37 FR 20160) on hexachlorophene that limit all products containing more than 0.1 percent hexachlorophene to prescription use. The comments objected to the Antimicrobial I Panel's classification of hexachlorophene in Category II in its advance notice of proposed rulemaking for OTC topical antimicrobial drug products (September 13, 1974; 39 FR 33103). One comment to the tentative final monograph for OTC antimicrobial drug products objected to the agency's statement, at 43 FR 1213, that the Commissioner "sees little or no need to use antimicrobial soaps on infants." The comment cited previously submitted data which demonstrate that hexachlorophene-containing bar soaps, powders, lotions, and solutions reduce staphylococcal infections in the nursery and are helpful in the prevention and management of diaper rash. The comment stated that between 1949 and 1972 many hundreds of thousands of newborn infants routinely underwent antiseptic care (total body bathing) with hexachlorophene preparations. According to the comment, this use resulted in the reduction and control of staphylococcal cross-infection and sepsis in newborns. Several submissions stated that the need and benefits derived from hexachlorophene products have been clearly documented by the staphylococcal epidemics that followed the removal of hexachlorophene products from hospital nurseries in 1971 as a result of FDA action. One of the comments submitted additional data to support the safety of hexachlorophene in infants, including a retrospective study by Plueckhahn and Collins on 3 percent hexachlorophene in baby bathing (Ref. 3), an unpublished study by Plueckhahn of hexachlorophene blood levels in infants receiving routine antiseptic skin care (Ref. 4), and a comprehensive review article by Plueckhahn on the safety and effectiveness of hexachlorophene in infants (Ref. 5). While acknowledging that toxicity can result from use of 3 percent hexachlorophene in premature infants or infants with skin excoriations, or from the use of high (6 percent) concentrations of hexachlorophene, this comment nevertheless contended that the value of hexachlorophene far exceeded its drawbacks. The comment specifically quoted Plueckhahn's and Collins' conclusions (Ref. 3) that "there is no rationale for restricting the dermal use of 3 percent hexachlorophene emulsions in the care of normal infants."

The agency agrees that the submitted studies indicate that hexachlorophene 3 percent can be effective in preventing staphylococcal skin infections in infants. Hexachlorophene may also be effective in preventing or treating diaper rash (Refs. 6 through 10). Nevertheless, as discussed below, the agency is not classifying hexachlorophene in Category I for OTC use in infants because its toxicity prevents safe use by the layman.

The deaths of 36 infants were reported in France in 1972 from poisoning by a topical baby powder inadvertently contaminated with up to 6 percent hexachlorophene (Ref. 11). Goutieres and Aicardi (Ref. 12) reported on 18 children between 3 months and 3 years of age with normal skin who were accidently intoxicated by this hexachlorophene-contaminated powder. Four cases with spinal cord involvement died of cardiorespiratory arrest and two others remained paraplegic. The powder had been applied to the napkin area several times a day and allowed to remain between changes. Seventeen of the children developed severe erythema in the napkin area resembling second-degree burns. Erythema preceded the neurological signs by 3 to 15 days in 6 cases, followed the neurological signs in 4 cases, and occurred simultaneously or at unknown times in the remaining cases. The authors felt that the higher concentration hexachlorophene, the prolonged contact with the skin, and the cutaneous erosion induced by hexachlorophene may have all resulted in increased absorption of hexachlorophene.

Shuman, Leech, and Alvord (Refs. 13 and 14) conducted a retrospective pathological study in human infants who died of other causes and showed a correlation of brain lesions with hexachlorophene-bathing. Bruch (Ref. 15) notes that topically applied hexachlorophene was proven to result in levels of hexachlorophene in the body high enough to be able to produce neurologic disorder and morphologic changes.

Several investigators have noted that the risk of hexachlorophene toxicity increases in the presence of dermal rashes, abrasions, burns, or wounds (Refs. 11, 12, 16, and 17). Maibach and Hacker (Ref. 18) have also suggested that the regular use of antibacterial agents such as hexachlorophene on the easily penetrated skin of the scrotum may be a significant cause of inflammation leading to secondary infection.

With whole body bathing of infants to prevent staphyloccal skin infections, most recommendations would limit such use to only specific situations in hospital nurseries. For example, as noted above Shuman, Leech, and Alvord (Refs. 13 and 14) found that repeated whole body bathing (by applying an undiluted preparation containing 3 percent hexachlorophene to the whole body except the face) in premature infants correlated with lesions in the brainstem reticular formation. The authors concluded that, based on their findings, hexachlorophene should not be used at all in the small premature infant and the amount used in near-term or full-term infants should be markedly decreased and rinsed off thoroughly.

Imperato (Ref. 19) recommended prophylactic daily bathing of healthy newborn infants using 3 percent hexachlorophene as a control measure during a staphylococcal epidemic in a hospital nursery. Imperato also recommended that hexachlorophene bathing should be discontinued upon discharge from the nursery, and stated that no hexachlorophene-containing preparation should routinely be provided for bathing at home.

The Committee on Fetus and Newborn of the American Academy of Pediatrics agreed that during outbreaks of epidemics of *S. aureus* infection in a hospital nursery, one possible measure undertaken could be brief institution of a program of total body bathing with a solution of not more than 3 percent hexachlorophene (Refs. 20 and 21). Under this program, the application would be limited to full-term infants, thoroughly washed off after the application, and applied no more than two times to each infant.

In the tentative final monograph for OTC topical antimicrobial drug products (42 FR 1210 at 1220), the agency, in response to a comment objecting to the classification of hexachlorophene as a prescription drug, concluded that there was no convincing basis for changing the ingredient's classification as set forth in the Federal Register of September 27, 1972 (37 FR 20160).

The agency does not consider the additional data submitted by the comment as sufficient to support the safe use of hexachlorophene on infants. The agency finds a lack of sufficient data to support the conclusion reached by Plueckhahn and Collins that the benefits of the use of hexachlorophene in normal newborn infants far outweigh any possible risks from central nervous system vacuolation (Ref. 3). The study which serves as the basis for their conclusion lacks essential details of hexachlorophene usage, such as the amount of hexachlorophene used, the length of exposure, rinsing methods, if any, and frequency of application. Plueckhahn and Collins concluded that infants having a low birth weight (less than 2,000 grams (g)) were susceptible to central nervous system vacuolation after hexachlorophene skin care; however, the agency finds that they made no comparison of skin conditions or physical differences between infants weighing less than 2,000 g and those weighing more than 2,000 g. Although this study suggests that a low birth weight may account for the development of vacuolation, the data are insufficient to support this theory.

Plueckhahn and Collins also state in their study (Ref. 3) that it is possible the central nervous system vacuolation "is not directly due to high blood and tissue hexachlorophene concentrations and is not a measure of neurotoxicity." They contend that the vacuolation may be a transient edema without overt symptomatology. However, this conclusion was not substantiated by the data, and extensive behavioral tests on animals exhibiting such histological changes would be essential to substantiate the authors' conclusion. The agency is aware of one such study conducted in rats where orally administered hexachlorophene was shown to have an adverse effect on behavior and other central nervous system functions even after the drug was discontinued and the animals appeared normal (Ref. 22).

The unpublished study by Plueckhahn (Ref. 4) involved 152 infants weighing more than 2,000 g who received routine antiseptic skin care with 3 percent hexachlorophene. The blood hexachlorophene concentration obtained by "heel pricks" reached a plateau of about 0.3 parts per million (ppm) after three or more washings and did not increase significantly with additional washings. However, this study failed to report the skin condition, weight, or blood levels of the individual infants tested.

The review article contained an unpublished study by Plueckhahn (Ref. 5) that discussed two groups of infants who received routine antiseptic skin care with either 3 or 0.75 percent hexachlorophene. The blood analysis showed absorption of hexachlorophene, with lower blood levels after use of 0.75 percent hexachlorophene than with 3 percent hexachlorophene. Plueckhahn concluded that hexachlorophene blood levels reach a maximum during the first week of skin care. The agency believes that this statement should be qualified to point out that, with the limitations of the study, the observation of maximum blood levels of hexachlorophene are reached within 1 week. Only 22 of the 722 blood specimens were taken after 8 days. Deficiencies in the study are that skin area, skin condition, weight of infant, and rinsing techniques were not described. Also, the blood level data appear to contradict the suggestion made in the study described above (Ref. 3) that infants weighing more than 2,000 g do not absorb enough hexachlorophene to cause central nervous system vacuolation. The data show increasing blood levels of hexachlorophene through day 7 or 8 even though applications were made only on alternate days (Ref. 5). Other data reviewed by the agency suggest rapid metabolism and elimination (Ref. 23), but these data from alternate day applications make the metabolism data a weaker case.

Another study in the review article listed blood hexachlorophene concentrations for 33 infants receiving routine skin care with 0.5 percent hexachlorophene talcum powder for 9 to 14 days (Ref. 5). The ages of the babies were not listed and the frequency of the diaper area powdering cannot be determined from the data presented. Furthermore, an increasing blood concentration with time can be observed in many of the infants studied, but the author did not reach any conclusions from this particular study.

One conclusion by Plueckhahn is that "immediate or long term adverse clinical effects or neurological manifestations have not been seen in low birth weight infants with blood hexachlorophene concentrations ranging from 0.690 ppm to 1.59 ppm during routine antiseptic skin care" (Ref. 5). In the earlier study

(Ref. 3), Plueckhahn and Collins briefly discussed 12 infants from 2 separate studies who received a total body bathing with hexachlorophene at least four times and then were followed-up clinically for 2 to 12 years. The infants were reported to have developed normally, but no details of the follow-up were presented.

The agency does not find the limited long-term data adequate proof that there are no long-term adverse effects from hexachlorophene usage. The agency also questions the author's statement that "spongy vacuolation during routine antiseptic skin care with 3.0 percent hexachlorophene emulsions does not occur in normal newborn infants weighing more than 2,000 g at birth" (Ref. 3). This statement was based solely on the results of infant autopsies and cannot be applied to normal newborns.

Under existing agency regulations in 21 CFR 250.250, hexachlorophene is contraindicated for use on burned or denuded skin or on mucous membranes and for routine prophylactic total body bathing. Based on this regulation and the discussion above, the agency also concludes that hexachlorophene is contraindicated to either prevent or treat diaper rash. The agency further restates that total body bathing of infants to prevent staphylococcal skin infections for specific situations in hospital nurseries should be limited to use only under medical supervision with appropriate labeling for safe and effective use by practitioners as described under § 250.250.

The agency concludes that hexachlorophene is Category II for OTC drug products with diaper rash claims or other claims concerning prevention of staphylococcal skin infections in infants because of safety risks.

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H. Comments on Methylbenzethonium Chloride

11. Several submissions to the Antimicrobial I Panel (Ref. 1), the Antimicrobial II Panel (Ref. 2), and the Miscellaneous External Panel (Ref. 3) were for products containing methylbenzethonium chloride with diaper rash claims. The products included an ointment containing 0.1 percent methylbenzethonium chloride, zinc oxide, calamine, and eucalyptol; a cream containing 0.1 percent methylbenzethonium chloride, 20 percent zinc oxide, 5 percent cod liver oil with vitamins A and D, and 5 percent calcium caseinate powder; an ointment containing 0.1 percent methylbenzethonium chloride, 17.5 percent white petrolatum, and 12 percent glycerin; a lotion containing 0.068 percent methylbenzethonium chloride in a water and oil emulsion with an oxycholesterin absorption base and magnesium citrate; a lotion containing methylbenzethonium chloride, methylparaben, propylparaben, and chlorobutanol; and a powder containing 0.059 percent methylbenzethonium chloride in a corn starch base.

A submission from one company (Ref. 4) included labeling bearing general antiseptic claims such as "antiseptic ointment—aids in the prevention and treatment of irritated skin in such conditions as diaper rash * * *."

A second company with submissions for several products (Ref. 5) focused on ammonia dermatitis in diaper rash, and stated that methylbenzethonium chloride, when released from ointment, cream, and powder bases, or from impregnated diapers, acts presumably by killing microorganisms in urine and feces that produce ammonia and other (as yet, unspecified) irritating agents. This company contended that the consistent finding in the controlled clinical studies in its submissions is that methylbenzethonium chloride is an effective agent for the treatment of ammonia dermatitis and that it can be used prophylactically as a means of reducing the incidence of ammonia dermatitis.

Methylbenzethonium chloride has been reviewed for safety for topical use in two other OTC drug rulemakings. In the advance notice of proposed rulemaking for OTC topical antimicrobial drug products (September 13, 1974; 39 FR 33103), the Antimicrobial I Panel concluded that this ingredient and two other quaternary ammonium compounds at a concentration not greater than 1:750 (0.13 percent) could be

regarded as safe as a skin wound cleanser provided that the product is not used repeatedly, covered with occlusive bandaging, or used in deep or extensive wounds (39 FR 33116). However, the Panel concluded that further toxicity data characterized by the absorption and systemic toxicity in a rodent and nonrodent species should be generated prior to the placement of these quaternary ammonium compounds into Category I for use other than as a skin wound cleanser (39 FR 33132). In the tentative final monograph for OTC topical antimicrobial drug products (January 6, 1978; 43 FR 1210), the agency did not include recommendations for further animal studies and stated that the systemic toxicity of quaternary ammonium compounds in animals is low and is indicative of and reflects the surfactant nature of the molecule (43 FR 1236). The agency stated that even though specific absorption and systemic levels in humans have not been reported for the three quaternary ammonium compounds reviewed, considering the concentrations applied, and extrapolating from animal studies, toxic effects at use levels would be unlikely (43 FR 1237). However, both the Panel (39 FR 33132) and the agency (43 FR 1237) noted that there are many reports on the irritating nature of the quaternary ammonium compounds on the skin, mucous membranes, and the eye and that the degree of irritation increases when quaternary ammonium compounds are used under occlusion.

OTC topical use of methylbenzethonium chloride for controlling cradle cap was reviewed by the Miscellaneous External Panel in the advance notice of proposed rulemaking for OTC drug products for the control of dandruff, seborrheic dermatitis, and psoriasis (December 3, 1982; 47 FR 54646 at 54677). The Panel evaluated a submission (Ref. 6) for a product containing methylbenzethonium chloride 0.07 percent in an emulsified petrolatum base with label directions to apply 3 times daily for 3 days for treatment of cradle cap and to apply 3 times weekly to prevent recurrence. The Panel concluded that this product was safe for controlling cradle cap (47 FR 54677).

NDA's were approved on the basis of safety for two OTC drug products containing methylbenzethonium chloride for use on infants for diaper rash: one in 1947 for a diaper impregnator rinse (1:25,000 dilution) (Ref. 7), and the other in 1948 for a topical diaper rash ointment at a 0.1 percent concentration (Ref. 8). While there have been reports of skin irritation or necrosis resulting from topical treatment, especially under occlusion, with other quaternary ammonium compounds (Refs. 9 through 12), there is little evidence that this problem has occurred with methylbenzethonium chloride in the 40 years that it has been marketed for use for diaper rash.

The data in the submissions (Refs. 1, 2, and 3) to the OTC panels included reports of 17 controlled and uncontrolled trials involving over 7,000 subjects in which the use of various dosage forms (ointments, creams, lotions, powders, and solutions for topical use; and final rinses for diapers) of methylbenzethonium chloride were tested on over 4,000 infants and children to prevent or treat diaper rash (Refs. 13 through 26). In all these studies, there were no reports of adverse reactions attributable to methylbenzethonium chloride.

Several of these studies (Refs. 15, 20, and 24) were for a prolonged duration. For example, both Lipschutz and Agerty (Ref. 15) and Meadows (Ref. 20) studied the use of a prophylactic regimen for diaper rash that included daily use of hexachlorophene skin cleanser and methylbenzethonium chloride in a lotion, ointment, cream, or diaper rinse. Lipschutz and Agerty (Ref. 15) evaluated the prophylactic regimen on 200 children ranging from 2 months to 2½ years of age. Each child remained in the study for 6 months. The authors did not report any medical problems attributable to failure of the regimen and did not report any primary or secondary skin sensitivity. Meadows (Ref. 20) evaluated the same prophylactic regimen on 100 infants, beginning at birth and followed at regular intervals for 3 to 24 months (average 10.7 months). The author did not report any cases of intolerance to the skin care products and recommended that this home prophylactic antiseptic skin care should continue until the child is toilet trained.

Wahlberg (Ref. 11) reviewed the literature in 1962 and reported only 7 clinical cases of hypersensitivity to quaternary ammonium compounds. None of these cases involved methylbenzethonium chloride. In addition, 5 studies (Refs. 13, 16, 17, 19, and 22) included patch tests on a total of 450 infants and indicated that methylbenzethonium chloride was not a significant sensitizer. Lipschutz and Fischer (Ref. 16) used patches treated with methylbenzethonium chloride (1:1,800) in a corn-starch-base dusting powder and skin-tested 50 infants and children ranging in ages from 3 weeks to 5 years. The patches were left in contact with the skin on an unspecified place for 48 hours. One child developed an erythema that cleared in 48 hours. When the patches were reapplied 10 days later on the same children, no reactions were noted. These authors also reported that another investigator had found the methylbenzethonium chloride powder to be hypoallergenic. Chiara (Ref. 13) patch-tested 50 newborn infants with a lotion containing 0.068 percent methylbenzethonium chloride by applying gauze pads saturated with the lotion to the area between the scapulae and examining the areas after 48 hours. The patches were reapplied in 2 weeks and evaluated again after 48 hours. No evidence of irritation or sensitivity was noted in any of the infants. Grossman (Ref. 17) patch-tested 100 newborn infants with an ointment containing 0.1 percent methylbenzethonium chloride in a cod liver oil base. The patches were left on an unspecified area for 72 hours, removed for 1 week, and reapplied for 72 hours. No evidence of perianal sensitivity was noted.

Niedelman and Bleier (Ref. 19) patch-tested 50 infants and children with an ointment containing 0.1 percent methylbenzethonium chloride. The patch-test was applied in the usual manner on the back or on the arm with a half-inch square gauze covered with wax paper and held in place by adhesive tape. In 10 subjects the patch was removed after 24 hours, in 20 subjects after 48 hours, and in the remaining 10 subjects after 72 hours. There were no reactions to the ointment. Benson et al. (Ref. 22) patch-tested 180 children and infants and 20 newborn infants with a solution of 1:5,000 methylbenzethonium chloride on 1 inch square gauze patches that remained wet and in contact with an unspecified area of skin for 24 hours. In 100 of the infants and children, the patch test was repeated in 10 days. No irritating effects were noted. Maibach (Ref. 27) reported that minimal irritation was observed when 0.2 mL of a 0.5 percent methylbenzethonium chloride solution impregnated on a 2-centimeter square patch of nonwoven fabric was applied to the backs of adult volunteers and remained under occlusion for 21 days. Each patch was renewed every 24 hours after evaluation.

Most of the topical preparations studied (as described above) were at concentrations of 0.1 percent or less, although there were some reports of more concentrated preparations being used. For example, Vignec (Ref. 25) used an antiseptic liquid containing 0.5 percent methylbenzethonium chloride and other ingredients for 7 to 14 days on 138 infants suffering from diaper irritation, minor skin conditions, and

excoriation. He concluded that the drug was safe because at no time did it produce irritation or allergic reactions. Although this report suggested that concentrations up to 0.5 percent would not be irritating for use on infants for diaper rash, it only involved short-term use.

Although the Miscellaneous External Panel recommended that methylbenzethonium chloride is safe for use in treating cradle cap, other panels have raised concern about repeated use and use under an occlusive dressing. When used for treating and/or preventing diaper rash, the product is likely to be used for a long period of time, possibly over a large area and on more sensitive skin, and will be used under occlusion, i.e., diapers. However, with the exception of irritation tests conducted by Niedelman and Bleier (Ref. 19), which were done under occlusion, the authors of the other studies (Refs. 13, 16, 17, and 22) do not state whether or not occlusion was used in their tests to maintain the product in close contact with the skin. Also, the authors do not specify whether any of the patch-tests were applied to the infants' diaper area, which is more sensitive than other areas of the body. Therefore, the agency is not able to reach any conclusions about the sensitizing potential of the ingredient under the occlusive conditions found in the diaper area when this ingredient is used chronically on infants and children.

The agency has determined that additional data are needed to demonstrate the safety of methylbenzethonium chloride or other quaternary ammonium compounds for use in diaper rash drug products for chronic use on infants and children. Studies need to be done to determine the degree of absorption from broken skin (as evidenced by blood levels) and the relationship between these blood levels and the blood concentration that produces no adverse effect in animals. In addition, studies are needed to determine the skin irritation and sensitization potential in infants when the ingredient is applied chronically under occlusion as occurs in the diaper area.

As part of the agency's Drug Efficacy Study Implementation (DESI) program, the National Academy of Sciences-National Research Council (NAS–NRC) Panel on Drugs Used in Dermatology II evaluated the ointment product that contained 0.1 percent methylbenzethonium chloride. The NAS–NRC Panel also evaluated the diaper rinse product that contained 12.7 percent methylbenzethonium chloride (1 tablet diluted in 2 quarts of water, providing an approximately 1:25,000 solution for six diapers). The label claims for these products include: "quickly relieves diaper rash," "antibacterial," "prevent diaper rash," and "eliminates the cause of diaper rash (ammonia dermatitis)," (Refs. 28 and 29). The NAS–NRC Panel categorized both products as "effective but * * *" and explained that the products' efficacy was adequately documented, but the labeling implied that ammonia is the only cause of diaper rash, which is not the case. That Panel also stated that with appropriate rephrasing of the labeling, it could consider these products effective. Subsequently, in the **Federal Register** of July 3, 1971 (36 FR 12705), the agency stated its position on the NAS–NRC reports and classified these products as "possibly effective" in preventing diaper rash and eliminating the cause of diaper rash (ammonia dermatitis). The agency also stated that these products lacked substantial evidence of effectiveness when labeled for use as antiseptics, disinfectants, or general antimicrobial agents.

With respect to the claim for methylbenzethonium chloride use against diaper rash caused by ammonia-producing microorganisms, the agency concluded that the manufacturer needed to show efficacy against all the organisms that can produce ammonia. The agency also determined a need to demonstrate efficacy under use conditions, in vitro and in vivo, in the presence of appropriate inactivators, e.g., soap, anionic detergents, fecal material, urine, cotton, hard water. The agency was concerned about reports that quaternary ammonium compounds are readily inactivated by many substances that may be encountered during use in the diaper area, e.g., gauze, cotton, fecal material, blood, soap, dirt (Refs. 30 through 33). However, Walter (Ref. 34) questioned whether some of the reports of inactivation of quaternary ammonium compounds are accurate. He felt that these reports were based on inadequate dilutions and improper use of quaternary ammonium compound disinfectants, especially in hospitals.

The antiseptic action of methylbenzethonium chloride, a quaternary ammonium compound, can be altered by anionic detergents, including soap (Ref. 30). Accordingly, data were needed to show that antibacterial activity still occurred when topical products were applied to detergent- or soap-washed skin or when diapers that had been laundered with detergent or soap were treated with a diaper rinse containing methylbenzethonium chloride.

Subsequently, the company submitted additional information (Ref. 35) to the DESI rulemaking to show evidence of (1) activity of methylbenzethonium chloride against urea-splitting organisms other than *B. ammoniogenes* and *P. mirabilis*, specifically pseudomonas, micrococci, and diphtheroids, (2) residual antibacterial activity in diapers rinsed in methylbenzethonium diaper rinse after detergent or soap laundering, and (3) evidence of activity of methylbenzethonium chloride on the skin of infants washed with detergents or soaps. Agency action regarding these products under the DESI program was subsequently deferred to the OTC drug review (January 11, 1974; 39 FR 1580).

Regarding methylbenzethonium chloride activity against urea-splitting organisms other than *B. ammoniogenes* and *P. mirabilis*, the company contended that evidence of microbiologic activity of methylbenzethonium chloride against pseudomonas and various micrococci is amply supplied in articles by Nagamatsu, Johnson, and Silverstein (Ref. 36), and by Lawrence (Ref. 37). The Nagamatsu, Johnson, and Silverstein study was also cited by the NAS–NRC Panel to document its "effective but * * *" classification. This uncontrolled study involved the prophylaxis and treatment of 23 incontinent patients aged 39 to 75 years with skin excoriation, using a 1:5,000 solution of methylbenzethonium chloride to impregnate dressings, diapers, or towels. A water-miscible ointment containing 0.1 percent methylbenzethonium chloride was used as an adjunct where ulceration occurred. The authors chose this treatment method because they had found that a urinary culture of these patients always revealed the presence of ammonia-splitting organisms within the urine itself. They related this to Cooke's work on ammonia-caused diaper rash due to *B. ammoniogenes* and other studies on use of methylbenzethonium chloride impregnated diapers in children with diaper rash. The authors felt that if methylbenzethonium is equally effective against all the ammonia-producing organisms, then treatment with dressings impregnated with the ingredient would be equally effective treatment for their patients with urinary excoriation. The authors found methylbenzethonium chloride effective in vitro (using broth cultures) against all the urea-splitting organisms isolated from their patients. The authors

provided a table listing the bacteriostatic and bactericidal dilutions of methylbenzethonium chloride against some of the more common urea-splitting isolates, including *P. vulgaris, Streptococcus faecalis, Pseudomonas Pyocyanea, Alcaligenes faecalis, Aerobacter aerogenes,* and *S. viridans.* Lawrence (Ref. 37) found methylbenzethonium chloride to be more effective than neomycin in minimum inhibition concentration in vitro tests against all the gram-positive and gram-negative organisms tested, which included *B. ammoniagenes, S. aureus, Salmonella typhosa (S. typhosa), P. mirabilis, P. aeruginosa, Bacillus cereus (B. cereus), Bacillus subtilis (B. subtilis), E. coli, P. vulgaris, Salmonella cholerae-suis (S. cholerae-suis), Salmonella pullorum (S. pullorum),* and *Shigella dysenteriae (S. dysenteriae).* Although the company was unable to find any data on diphtheroids, the agency notes that Leyden (Ref. 38) has subsequently stated that *B. ammoniogenes* is a diphtheroid, for which in vitro data are available. Therefore, the agency agrees that these studies (Refs. 36 and 37) demonstrate that methylbenzethonium chloride has in vitro bacteriostatic activity against many ammonia-producing bacteria.

The agency does not, however, consider these data sufficient to establish effectiveness. In the discussion on Cooke's ammonia theory of diaper rash (see comment 2 above), it was noted that this theory has been questioned by more recent studies. Thus, any claims concerning the ammonia theory must be supported by clinical studies on infants that include bacteriological studies to correlate a reduction in ammonia-producing bacteria with a clinical improvement in the diaper rash (see comment 2 above). Therefore, in vitro tests are not sufficient to prove effectiveness for ammonia-caused diaper rash.

For a discussion of residual antibacterial activity in diapers rinsed in methylbenzethonium chloride after detergent or soap laundering, see comment 12 below.

As to activity of methylbenzethonium chloride on the skin of infants washed with detergents or soaps, the company stated that no studies were specifically directed to evaluating the effect of residual soap or detergent on babies' skin on the activity of its products. However, the company specifically cited the studies by Lipschutz and Fischer (Ref. 16) and Benson et al. (Ref. 23) as supporting successful prophylaxis or treatment of diaper rash presumably in the presence of residual soap or detergent on the skin.

The agency has evaluated the studies submitted by the company that were cited by the NAS-NRC Panel as well as other data submitted to the OTC drug review in which methylbenzethonium chloride was used to treat or prevent diaper rash. The following comments are limited to those drug products intended for direct application to the skin of infants. Studies on the use of methylbenzethonium chloride for diaper-rash-like skin conditions in incontinent adults are discussed in comment 13 below. Diaper rinses intended for use to treat diapers are discussed in comment 12 below.

The agency finds that the studies pertaining to the treatment or prevention of what is loosely referred to as diaper dermatitis suffer from the major defect of lack of definition. Diaper dermatitis is not a single entity, and none of the authors has given specific parameters for the diagnosis of the condition. In the studies on ammonia dermatitis, no attempts were made to assay levels of ammonia or ammonia-forming bacteria on the skin or diaper either before or after therapy.

Most of the studies were conducted in the late 1940's to early 1960's when the concept of a double-blind, controlled protocol was not as widely recognized as it is today. In many of these studies, instead of using a control of the vehicle without the active ingredient, some other preparation was used as the control, such as mineral oil, petrolatum, a product containing another antimicrobial ingredient, or soap and water. In addition, several of the other ingredients contained in the methylbenzethonium chloride-containing preparations are being reviewed as active ingredients in the skin protectant segment of the diaper rash rulemaking, with some being classified as Category I. Some examples are cod liver oil, zinc oxide, petrolatum, calamine, and corn starch. Because these skin protectant ingredients contribute a substantial benefit for treating or preventing diaper rash, appropriate vehicle controls must be used to support conclusions regarding methylbenzethonium chloride's contribution to the product's effectiveness. Furthermore, in several of the studies, more than one dosage form of methylbenzethonium chloride was used as part of a "skin care regimen." In some of the studies (Refs. 15 and 20), a hexachlorophene detergent skin cleanser was also used in addition to the various methylbenzethonium chloride products. Therefore, many of the studies are not considered adequate to establish the contribution of methylbenzethonium chloride.

Several studies (Refs. 13, 17, and 21) were conducted on newborn infants while still in the hospital. Two of the studies (Refs. 13 and 21) specifically stated and one study (Ref. 17) implied that regular soap and water baths were not given to the infants. This regimen is not typical of the conditions of home use of diaper rash products and would not answer agency concerns about the possibility of residual soap on the skin inactivating methylbenzethonium chloride.

Because of the various problems with the studies above, the agency believes the studies by Bleier and Niedelman (Ref. 14) and by Lipschutz and Fischer (Ref. 16) provide the most useful information. Bleier and Niedelman (Ref. 14) conducted a controlled study on 90 infants diagnosed as having ammonia dermatitis. Fifty-eight infants were treated with an ointment containing 0.1 percent methylbenzethonium chloride and 32 infants were treated with the ointment base alone as controls. The authors only stated that for the methylbenzethonium chloride group the treatment was 1 day to 3 weeks and did not specify any time period for the control group. The study was conducted in a hospital, and the medical and nursing staff were unaware of which ointment was being used. Although no criteria were given for the different grades of severity in the infants studied, the authors did group them as having mild rash or severe rash. Of the 58 infants treated with the active ingredient, 42 (72 percent) were classified as having mild diaper rash, while 16 (28 percent) were classified as having severe diaper rash. At the end of the treatment period, 53 percent were considered healed, 41 percent were improved, and 5 percent were not improved. The authors noted that improvement was most significant in the severe group, where 11 of 16 (69 percent) were healed and 5 (31 percent) were improved. Of the 32 infants in the control group, 12 (37 percent) had mild diaper rash and 20 (63 percent) had severe diaper rash. Although the authors did not state the time period of treatment in the control group, there was a 25 percent improvement (6 in the mild group and 2 in the severe group). The agency notes that there was a substantial disparity between the percent of infants who had severe dermatitis and received active treatment (16 of 58 or 28 percent) and those who received the vehicle control (20 of 32 or 63 percent). While the authors noted

that many antiseptics lose some of their activity in the presence of organic matter, they concluded that this study demonstrated that the ointment containing methylbenzethonium chloride was not inactivated on the skin.

Lipschutz and Fischer (Ref. 16) evaluated methylbenzethonium chloride in a corn starch dusting powder. In vitro bacteriological studies were performed and demonstrated that the growth of innoculated *B. ammoniagenes* was markedly inhibited in diapers that were dusted with the corn starch powder containing methylbenzethonium chloride. However, there was good growth of organisms in the control diapers that were dusted with either 5 percent borated talc or plain corn starch dusting powder. The authors then evaluated the use of the methylbenzethonium chloride corn starch dusting powder for the treatment of ammonia dermatitis and intertrigo in infants 3 months to 2 years of age. The criteria for diagnosis of ammonia dermatitis were location (areas of skin in contact with urine-soaked diapers or bed clothes), type of rash (mild, erythema; moderate, papular vesicular, pustular; severe, ulceration including meatus ulcer), and ammonia odor. The criteria for diagnosis of intertrigo were location (folds of skin, especially the groin), type of rash (erythema and exudation limited to the folds), and type of infant (usually obese infants improperly cleaned and bathed). All infants were treated for 10 days, with powder dusted on the infant after each diaper change and at bedtime (an average of seven times a day). Diapers were washed with a mild soap and rinsed thoroughly. Diapers were changed usually within one-half hour after soiling except during sleep. In the intertrigo study, 2 groups of 50 infants each were tested: (1) One group using methylbenzethonium chloride-corn starch dusting powder showed 92 percent cleared, and (2) the other group using only a corn starch powder control showed 84 percent cleared. In the ammonia dermatitis study, 2 groups of 50 infants each were tested: (1) One group using methylbenzethonium chloride-corn starch dusting powder showed 78 percent cleared, and (2) the other group using only a commonly used corn starch powder for the control showed 46 percent cleared.

Lipschutz and Fischer (Ref. 16) also evaluated methylbenzethonium chloride in a water miscible ointment for the treatment of ammonia dermatitis. One hundred infants were studied over a 3-month period. Infants were alternately treated with methylbenzethonium chloride ointment or the base without the active ingredient. In all cases the ointment was applied after each diaper change and on retiring for the night (an average of 7 times a day). Two groups of 50 infants each were tested: (1) One group using methylbenzethonium chloride ointment showed 82 percent cleared, and (2) the other group using ointment based control showed 42 percent cleared.

Although these studies (Refs. 14 and 16) were apparently well-controlled, they also suffer from defects. For example, in the Bleier and Niedelman study (Ref. 14) ammonia dermatitis was not defined, and the time until cure was not specified. In the Lipschutz and Fischer study (Ref. 16), the severity of the rash in each group was not indicated. In addition, in both of the above studies (Refs. 14 and 16), cleansing methods, such as exposure to soap and water, were not specified. Bleier and Niedelman simply state that "cleansing and attention to diaper changes were observed as usual." Lipschutz and Fischer state that "routine skin and diaper care was observed." Thus, these studies are not adequate to specifically evaluate the effect of residual soap or detergent on infant's skin on the activity of methylbenzethonium chloride.

Furthermore, neither Bleier and Niedelman (Ref. 14) nor Lipschutz and Fischer (Ref. 16) address the issue of bacterial involvement in diaper dermatitis or confirm the presence of ammonia or ammonia-forming bacteria on the skin either before or after therapy. While the data indicate that methylbenzethonium chloride may possibly be effective in the prevention or treatment of diaper rash, more information is needed before it can be placed in Category I for this use. The agency believes that further in vivo bacteriological studies are needed; specifically in vivo studies in infants to demonstrate the effect of the antibacterial activity of methylbenzethonium chloride on the skin flora and whether this effect correlates with clinical improvements in the diaper rash. Also bacteriological studies are needed to show that the long-term use of methylbenzethonium chloride does not result in potentially harmful changes in the normal flora of the skin in the diaper area.

The agency is concerned about the safety and effectiveness of antimicrobials being used regularly in the diaper area and whether such chronic use and the concomitant alteration of the dermal ecology could even aggravate diaper dermatitis.

Accordingly, the agency is classifying the quaternary ammonium compounds benzalkonium chloride, benzethonium chloride, and methylbenzethonium chloride for use in diaper rash drug products in Category III for both safety and effectiveness. (See also comments 5 and 6 above.)

References

(1) OTC Volume 020065.

(2) OTC Volumes 070074, 070075, 070076, 070078, 070079, 070080, and 070081.

(3) OTC Volumes 160027, 160242, 160243, 160244, 160245, 160246, 160247, 160320 and 160427.

(4) OTC Volume 160027.

(5) OTC Volumes 070074, 070075, 070076, 070078, 070079, 070080, 070081, 160242, 160243, 160244, 160245, 160246, 160247, 160320 and 160427.

(6) OTC Volume 160319.

(7) NDA 6168, Diaparene Antiseptic Diaper Rinse, Precrushed Tablets.

(8) NDA 6595, Diaparene Ointment.

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12. One manufacturer submitted data and information (Ref. 1) for two products (tablets and granules) containing methylbenzethonium chloride used as a final rinse to impregnate diapers. The tablets contained 12.7 percent methylbenzethonium chloride and the granules contained 6 percent methylbenzethonium chloride per teaspoon. The directions for preparing the diaper rinse stated one tablet or one level teaspoon of granules should be dissolved in 2 quarts of water for six diapers (or the equivalent of one pound in diapers). The products were labeled as an antibacterial diaper rinse and contained the following labeling claims: "Eliminates cause of diaper rash (ammonia dermatitis)," "* * * eliminates the cause of diaper rash by checking formation of urinary ammonia in wet diapers up to fifteen hours despite repeated wettings. Note absence of ammonia odor," "For ordinary protection, rinsing the night diapers with * * * is considered sufficient, when this is inadequate, rinsing of day diapers as well is recommended in addition to frequent diaper changes," and "As an added precaution against ammonia diaper rash, rinse baby's clothing and crib sheets with * * * ."

Data also were submitted for a commercial diaper rinse solution containing 25 percent methylbenzethonium chloride, 8.5 percent alcohol, and 0.8 percent trisodium ethylenediamine tetraacetate.[1] The directions for diluting the rinse solution to obtain 1 ounce per 100 pounds dry weight ranged from 1 ounce of rinse solution to 30 gallons of water for a 100 pound dry load of diapers to 5 ounces of rinse solution to 90 gallons of water for a 500 pound load. The labeling of this product stated that it "Eliminates cause of ammonia dermatitis."

The manufacturer contended that methylbenzethonium chloride released from impregnated diapers can effectively and safely ameliorate and prevent certain forms of diaper rash. The drug presumably acts by killing the microorganisms in urine and feces that produce ammonia and other (as yet, unspecified) irritating agents. The company contended that, on the basis of its submitted clinical studies, a 1:25,000 dilution of methylbenzethonium chloride should be classified in Category I as a diaper rinse.

As discussed in comment 4 above, the agency considers diaper rinse products with diaper rash claims to be drugs. As discussed in comment 11 above, the diaper rinse products are being evaluated separately from topical dosage forms containing methylbenzethonium chloride. As stated in comment 11, the agency did not concur with the NAS–NRC conclusion (Ref. 2) concerning the efficacy data in the NDA for methylbenzethonium chloride diaper rinse. Moreover, the NAS-NRC Panel's original evaluation of "effective but * * *" was changed to "possibly effective" in the DESI evaluation published in the Federal Register of July 3, 1971 (36 FR 12705). As discussed in comment 11 above, the agency concluded that data were needed to show efficacy against all the organisms that can produce ammonia. Also, efficacy needed to be demonstrated under use conditions. The agency also had concern that the labeling for the diaper rinse product did not caution that the antiseptic action of methylbenzethonium chloride can be altered by anionic detergents, including soap. The agency required data showing that methylbenzethonium chloride rinse is effective when used on diapers washed with anionic detergents or soaps even though the diapers are rinsed thoroughly before the diaper rinse is applied.

The effectiveness of a final diaper rinse containing methylbenzethonium chloride is based on the theory that "the positively charged functional portion of the quaternary molecule is attracted to and substantive to negatively charged fabric; it may be applied to the fabric from a quaternary solution by rinsing, padding, or spraying," (Ref. 3). Jenkins (Ref. 4) noted that when a quaternary ammonium fabric softener is added to the rinse water the cationic surfactant adheres to the fabric, surrounds its fibers, and acts as a lubricant so that the individual fibers are able to move freely, relative to each other, with the result of the material feeling soft. Jenkins also noted that quaternary ammonium surfactants have bacteriostatic activity and that some researchers had reported that treating diapers with fabric softeners tends to decrease both the incidence and exacerbation of diaper rash.

The agency believes that the following in vitro bacteriological studies on impregnated diapers indicate that the methylbenzethonium chloride final rinse is not inactivated by residual soap in clean-laundered fabric, and may maintain antibacterial activity in soiled diapers as well. The manufacturer submitted several studies (Refs. 5 through 15), in which in vitro tests were conducted on the antibacterial activity of fabrics impregnated with methylbenzethonium chloride, and on the use of methylbenzethonium chloride

[1] The agency has determined that the name "edetate trisodium" is the appropriate name for this ingredient.

soaks on soiled diapers. Lawrence and Maffia (Ref. 5) reviewed the literature in 1957 on the antiseptic impregnation of contaminated fabric (sick-room, diapers, etc.) and concluded that the quaternary ammonium compounds apparently were the most successfully used antiseptics in fabric impregnation because (1) with proper care they are nonirritating, nonallergic, nontoxic, and are adequate antibacterial agents, and (2) they tend to remain in the fabric despite many washings. The authors noted that washing cottons treated with quaternary ammonium compounds in cold, warm, or boiling water fails to remove the antibacterial properties of the textile. The authors concluded that washing with an anionic surface-active agent (true soaps, synthetic soaps) will, however, destroy the bactericidal properties of the quaternary ammonium compounds contained in the impregnated cloth.

In 1963, Lawrence (Ref. 6) compared two commercially available antibacterial diaper impregnation agents, methylbenzethonium chloride and neomycin sulfate. Several tests were carried out at various dilutions of the two agents, under laboratory conditions, under actual commercial laundry conditions, and on untreated "soiled" diapers. In one agar plate inhibition test, small sections of commercially-laundered diapers impregnated with methylbenzethonium chloride were tested with agar cultures of *B. ammoniagenes* or *S. aureus*. The methylbenzethonium chloride diffused into the agar from the fabric to produce a zone of inhibition around the diaper patches. Lawrence (Ref. 6) also tested untreated soiled diapers following the normal practice of first rinsing the feces from the fabric in a flush toilet. The diapers were still stained with fecal material and were kept at room temperature for 3 days. One diaper was then soaked in 2,000 mL of a 1:8,000 methylbenzethonium chloride diaper-soak; no organisms could be recovered from the solution after 1 hour. Lawrence concluded that the product containing methylbenzethonium chloride appears to remain the antibacterial agent of choice for impregnation of fabrics with minimal danger of patient sensitization and no reported incidences of the production of bacteria with increasing resistance to this germicide.

Soren (Ref. 7) used three dilutions of methylbenzethonium chloride to wash soiled diapers from hospital pediatric wards. Various in vitro tests were conducted on the diapers after washing in "Tide" detergent and rinsing in methylbenzethonium chloride (1:14,000, 1:9,500, and 1:7,000) final rinse to determine the presence of coliform bacteria, ammonia-forming bacteria, total bacterial count, and residual antiseptic properties in inhibiting *B. ammoniagenes*, *S. aureus*, and ammonia. Soren concluded that a 1:7,000 concentration of methylbenzethonium chloride in 3 quarts of water should be used as a rinse for each six diapers laundered in home automatic washing machines.

These studies demonstrate that final diaper rinses containing methylbenzethonium chloride do remain in the diaper and provide effective in vitro bacteriostatic activity provided they are used according to directions that alert the consumer not to mix anionic detergents, including soap, with these diaper rinses. However, the agency does not consider these data as sufficent to establish effectiveness for the treatment of diaper rash. As discussed above (see comment 2), it was noted that Cooke's ammonia theory of diaper rash has been questioned by more recent studies. Therefore, any claims concerning this ammonia theory need to be supported by clinical studies on infants. Such studies must include bacteriological studies to correlate a reduction in ammonia-producing bacteria with a clinical improvement in the diaper rash (see comment 2 above). Thus, in vitro tests alone on impregnated diapers are not sufficient to prove effectiveness for diaper rash.

The agency has evaluated the clinical studies (Refs. 14 through 18) submitted by the comment, including those (Refs. 14, 15, and 16) that were cited by the NAS–NRC Panel (Ref. 2), in which methylbenzethonium chloride was used as a final diaper rinse to treat or prevent diaper rash in infants. Most of these studies were conducted in the late 1940's to early 1960's, and frequently these studies were not controlled or involved a skin care regimen that included topical preparations in combination with the impregnated diapers. Benson et al. (Ref. 14) reported on 50 infants ranging in age from 1 to 18 months who were treated for moderate to severe ammonia dermatitis with diapers impregnated with methylbenzethonium chloride. Mothers were instructed to use 1 tablet in 2 quarts of water (approximately a 1:25,000 dilution) to impregnate up to six washed diapers. When the infants were observed at 3 days, 31 infants were improved, 18 were cleared, and one had no response. At 7 days, 49 were cleared and one still had no response. After stopping treatment, 14 infants returned in 2 to 4 weeks with a mild ammonia dermatitis which responded to retreatment with the impregnated diapers. The authors stated that many of the mothers noted that they no longer smelled ammonia in the diaper after treatment. Benson et al. (Ref. 15) later reported on 500 cases of mild, moderate, or severe ammonia dermatitis; 436 cleared within 1 week of treatment with methybenzethonium chloride impregnated diapers. The authors also stated in this second study that severe cases of ammonia dermatitis had been secondarily infected with *S. aureus* and various streptococci in which triple strength impregnated diapers (3 tablets to 2 quarts of water) gave the best results. However, the agency notes that both of these studies by Benson et al. (Refs. 14 and 15) were uncontrolled and did not give adequate details about the bacteriological skin counts or the methods used to cleanse the infants. The agency does not consider these studies adequate to demonstrate effectiveness.

Lipschutz and Agerty (Ref. 16) studied 170 institutionalized children from 2 months to 2½ years of age plus 30 children from private practice. The skin care regimen included daily bathing of each child with detergent skin cleanser containing hexachlorophene 0.5 percent, use of a methylbenzethonium chloride (1:1,800) corn starch base powder after each bath and diaper change, and use of a methylbenzethonium chloride cream or ointment (1:1,000) in the event of diarrhea or loose stools. The diapers and layette garments were impregnated with methylbenzethonium chloride (1:9,500) rinse solution. Four percent of the children on this prophylactic regimen developed a skin condition. The authors compared these results to an earlier control series of 100 cases over a comparable period in which only soap and water were employed prophylactically and the incidence of skin conditions was 29 percent. However, no further details were given concerning this control group, which apparently did not include vehicle controls. Because of the manner in which the study was conducted, the agency cannot determine which component(s) contributed to the benefit observed: the methylbenzethonium chloride in the impregnated diapers, the methylbenzethonium chloride in the topical preparations, the other antimicrobial (hexachlorophene), or the skin protectant ingredients in the topical preparations.

The study by Lipschutz and Fischer (Ref. 17), in which they evaluated the use of methylbenzethonium chloride-rinsed diapers for the treatment of ammonia dermatitis in infants 3 months to 2 years of age, indicates that this

method of using methylbenzethonium chloride may be of benefit for diaper rash. Three groups of 50 infants each were treated with a methylbenzethonium chloride (1:1,800) corn starch base dusting powder. The treatment of the diapers for the three groups differed: group 1 used diapers laundered with a mild soap and rinsed thoroughly, and the diaper rash cleared in 78 percent; group 2 used only night diapers rinsed in methylbenzethonium chloride, and the diaper rash cleared in 94 percent; and group 3 used all diapers rinsed in methylbenzethonium chloride, and the diaper rash cleared in 98 percent. A fourth group of 50 infants serving as an untreated control was treated only with a commonly used corn starch powder and with untreated diapers laundered only with a mild soap and rinsed thoroughly. The diaper rash cleared in 46 percent of the infants.

As discussed above in comment 11, the Lipschutz and Fischer studies suffer from a number of defects. For example, the severity of the rash in each group was not indicated, and the cleansing methods, such as exposure to soap and water, were not specified. The authors simply state that "routine skin and diaper care was observed." Also, the concentration of the methylbenzethonium chloride in the diaper rinse was not stated. It appears that the tablet dosage form submitted by the comment was used, presumably at the labeled directions of 1 tablet in 2 quarts of water for 6 diapers (1:25,000 dilution). The agency finds that although the Lipschutz and Fischer study showed that the methylbenzethonium chloride diaper rinse may have contributed to lowering the incidence of diaper rash, the diaper rinse was not tested separately from the methylbenzethonium chloride powder. Therefore, this study is not adequate to establish that methylbenzethonium chloride in a diaper rinse alone would be effective to treat or prevent diaper rash.

As discussed in comment 11 above, the data indicate that methylbenzethonium chloride may possibly be effective in the prevention or treatment of diaper rash. However, before this ingredient can be placed in Category I for this use, further in vivo bacteriological studies are needed, specifically in infants to demonstrate the effect of the antibacterial activity of methylbenzethonium chloride on the skin flora and whether this correlates with clinical improvements in diaper rash. None of the clinical studies (Refs. 14 through 18) discussed above addresses the issue of bacterial involvement in what they describe as ammonia dermatitis. Also, the proper effective concentration of methylbenzethonium chloride rinse needs to be determined. While the company stated that a 1:25,000 dilution was effective, some of the submitted studies (Refs. 6, 11, and 17) were conducted using stronger concentrations of 1:9,500 or less dilutions. Therefore, the agency is classifying methylbenzethonium chloride for use as a diaper rinse in Category III.

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13. Data (Ref. 1) were submitted for two products containing methylbenzethonium chloride with claims for treating and preventing infant diaper rash and similar conditions in older persons having poor bowel and bladder control. Additional data (Ref. 2) contained studies on the use of methylbenzethonium chloride in various dosage forms for skin care of incontinent, chronically ill, or geriatric patients.

The agency discussed the use of topical dosage forms and diaper rinses containing methylbenzethonium chloride in the treatment and prevention of diaper rash in infants and children in comments 11 and 12 above. In this comment, the agency discusses the use of topical products and fabric-impregnating final rinse dosage forms containing methylbenzethonium chloride for incontinent adult patients with skin problems similar to diaper rash.

The submitted studies (Refs. 3 through 11) include reports of the clinical use of various methylbenzethonium chloride products on 632 adult incontinent patients with no side effects noted. However, the agency does not consider these reports to be adequate safety data. The safety of methylbenzethonium chloride for use in infants and children is discussed in comment 11 above and the conclusion reached there (Category III) is applicable to the use of methylbenzethonium chloride in incontinent adults.

Also, as discussed in comment 11 above, the NAS–NRC Panel on Drugs Used in Dermatology II evaluated an ointment product and a diaper rinse product containing methylbenzethonium chloride. That Panel categorized both products as "effective but * * *" and cited several articles (Refs. 3 through 6) concerning skin care of adult or elderly incontinent patients. The agency did not concur with the NAS–NRC Panel, and in the **Federal Register** of July 3, 1971 (36 FR 12705), the agency classified these products as "possibly effective" in

preventing diaper rash and eliminating the cause of diaper rash (ammonia dermatitis). The agency concluded at that time that the manufacturer needed to demonstrate (1) efficacy against all the organisms that can produce ammonia, (2) efficacy under use conditions, and (3) that antibacterial activity still occurred when topical products were applied to detergent- or soap-washed skin or when fabrics that had been laundered with detergent or soap were treated with a fabric rinse containing methylbenzethonium chloride. These concerns applied equally to products containing this ingredient used on adults or children.

With respect to the antibacterial activity of methylbenzethonium chloride against ammonia-producing organisms in adult incontinents, the agency notes that Nagamatsu, Johnson, and Silverstein (Ref. 3) reported on the use of methylbenzethonium chloride impregnated dressings, diapers, or towels in 23 incontinent patients, aged 39 to 75 years, for prophylaxis or for treatment of skin excoriation. (This uncontrolled study is discussed in comment 11 above.)

Silverstein and Gips (Ref. 4) studied 11 incontinent patients ranging in age from 56 to 95 (median age 80 years) with skin graded according to the severity of the lesions, as follows: grade 0—no lesions, grade I—erythematous, edematous skin, grade II—superficial ulceration, and grade III—deep ulceration. All patients wore diapers impregnated with a 1:12,000 solution of methylbenzethonium chloride; the diapers were changed 6 to 8 times daily. At the discretion of the nurses, methylbenzethonium chloride powder (1:1,000 in corn starch and sodium bicarbonate) was applied to the interior of the diaper. Where actual ulceration was present, methylbenzethonium chloride 1:1,000 ointment was applied. Patients were observed on this therapy from 8 to 231 days (with a median study period of 104 days) with the following results: (1) Four patients without lesions (grade 0) continued to have good skin condition; (2) four patients with grade I or II lesions were cured in a median of 40 days, and on withdrawal of the ointment, the skin remained in good condition with the prophylactic use of the powder and impregnated diapers, (3) of the three patients with grade III ulceration—one patient had no significant lesions after 90 days (with the skin area in excellent condition at the end of 119 days when the patient died), one patient improved, with lesions upgraded to superficial ulcerations at 21 days (which was the end of the study period) while the third patient showed initial improvement but died before treatment was completed. Although this treatment phase was not controlled, eight of the patients were subsequently taken off the methylbenzethonium chloride regimen and continued in an untreated control phase for 62 days that consisted of their usual nursing care and untreated diapers. Four of the patients also received drying powders which did not contain significant amounts of antiseptics. During the untreated control phase, the severity of the lesions of seven of the eight patients changed from a grade 0 to I classification to a I or II classification. After this control period, the patients were then put back on methylbenzethonium chloride impregnated diapers solely for 28 days, after which all patients had clear skin. The authors noted that the nursing staff consistently reported the presence of ammoniacal odor a day or two after the discontinuance of the use of the treated diapers. The reports of the odor ceased upon resuming the use of the treated diapers.

Smigel (Ref. 5) treated 57 incontinent patients age 48 to 91 years (average age 75½ years) who had skin pathology due primarily to ammonia dermatitis, or secondarily aggravated by it. The skin pathology was classified in five degrees of severity: group A—erythema, group B—excoriations, group C—vesicles and pustules, group D—superficial ulcerations, and group E—deep ulcerations. All patients were treated with methylbenzethonium chloride rinsed linen and methylbenzethonium chloride powder used by rubbing it into the bed clothes rather than dusting it on the skin. More severe cases (half of group B, and all of groups C, D, and E) were also treated by application of methylbenzethonium chloride ointment. In all but 2 of the 57 patients, "urinary skin lesions" were either improved or completely healed; and a marked decrease in the usual offensive odor was noted. Although the treatment phase of the study was uncontrolled it was followed by a controlled prophylactic phase for 40 of the healed patients, in which 20 patients were continued on methylbenzethonium chloride rinsed linen and powder, and 20 were taken off the treatment ("controls"). After 4 weeks, recurrences to the first 3 degrees of skin pathology were noted in 11 (55 percent) of the controls and only in 2 (10 percent) of the patients who continued to receive the treatment. Although the author did not state the concentration of methylbenzethonium chloride in the various dosage forms, the trade products used were mentioned. The methylbenzethonium chloride concentrations in these products are 1:1,000 in the ointment, 1:1,800 in the powder, and 1:25,000 use concentration for the diaper rinse tablets.

Lawrence and Silverman (Ref. 6) reported on the effects of the use of prophylactic and therapeutic medications and appropriate supportive measures to prevent or treat skin problems of 111 bedridden, incontinent, geriatric patients. The patients were rotated through three 60 day phases of skin care: (I) normal hospital skin care and usual hospital laundry facilities; (II) normal hospital skin care and linens treated with methylbenzenthonium chloride solution; and (III) skin care with cream, powder, and lotion containing methylbenzethonium chloride, Ivory soap for bathing, and linen treated as in phase II. All linens for the hospital were washed in the laundry according to the standard laundry routine and were used for the phase I control. The linens used in phases II and III were treated by adding methylbenzenthonium chloride solution in a ratio of 2 ounces per 100 pounds of dry weight of linen in the final rinse for a period of 5 minutes. Laboratory examination of the treated fabric and control laundered fabric showed a decrease in the presence of bacteria in the treated fabric and demonstrated that patches of the treated fabric could inhibit the growth of *S. aureus* in an agar plate inhibition test. The agency believes that these results support the agency conclusions, in comment 12 above, that trace residual soap or detergent in previously laundered and rinsed fabric does not inactivate a subsequent final rinse containing methylbenzenthonium chloride and allows the ingredient to provide effective in vitro bacteriostatic activity.

This study (Ref. 6) was carried out on three 43-bed wards using the following 60-day rotation schedule: Ward A, phases I to III to II; ward B, phases II to I to III; and ward C, phases III to II to I. All patients were observed at 2-week intervals for ammoniacal or perianal dermatitis, secondary infections, intertrigo, decubitus ulcers, dry skin, or other special problems. Dermatological problems in the pretest period involved 71 percent of the patients; these problems decreased with the addition of methylbenzethonium chloride treatment as follows: Phase I, 62 percent; phase II, 21 percent; Phase III, 15 percent. At the post-test period (2 weeks following termination of the program), problem skin was observed in 56 percent of the patients, which the authors felt suggested a residual antiseptic effect.

The authors concluded that, even though the effect of methylbenzethonium chloride dermatologic products without treated linen was not studied, the results demonstrated the effectiveness of a prophylactic program in the care of bedridden, incontinent, convalescent, or geriatric patients. However, the agency notes that diagnoses of skin abnormalities prior to treatment and observations of the skin during the study were made by a single nonqualified observer, and that no bacteriological skin counts were done.

The agency finds that these studies seem to indicate that the impregnation of patient clothing, diapers, and bed linens with methylbenzethonium chloride could result in the reduction of the incidence of skin dyscrasias in long-term bedridden, incontinent patients and that the use of the methylbenzethonium chloride topical preparations may have contributed an additional benefit. The agency believes that these studies also appear to indicate that the effect any residual anionic soap on the skin would have on the antibacterial activity of methylbenzethonium chloride would be minimal. This finding is supported by the Lawrence and Silverman study (Ref. 6) which showed that the most significant improvement was in phase III of the study where it was specifically stated that Ivory soap (a known anionic soap) was used to bathe the patients. However, no bacteriological studies were done to confirm this. Therefore, the agency concludes that further data, particularly bacteriological skin counts, are needed to resolve the issues raised by the agency at the time of the DESI review regarding possible lessening of antibacterial effectiveness of methylbenzethonium chloride by residual anionic soap on the skin. Furthermore, in the studies where the condition was diagnosed as ammonia dermatitis, no attempts were made to assay levels of ammonia or ammonia-forming bacteria on the skin or clothing either before or after therapy. Therefore, because no bacteriological skin counts were taken on the patients, further in vivo bacteriological studies, specifically in incontinent adults, are needed to demonstrate the effect of the antibacterial activity of methylbenzethonium chloride on the skin flora and whether this correlates with the clinical improvements in skin problems similar to diaper rash. Also, as noted above, safety aspects need to be resolved. Therefore, the use of methylbenzethonium chloride for the treatment or prevention of adult skin problems similar to diaper rash is classified in Category III.

References

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I. Comment on Oxyquinoline

14. One manufacturer submitted data (Ref. 1) to the Miscellaneous External Panel for a combination product that included 0.1 percent 8-hydroxyquinoline and 0.05 percent 8-hydroxyquinoline sulfate with labeling claims for "diaper rash—acts as an antiseptic to help fight staph germs and other bacteria." The submission stated that confirmation of the antibacterial activity of hydroxyquinoline (or oxyquinoline) was substantiated in the medical and biological literature. A subsequent submission (Ref. 2) included reports providing additional data confirming the contribution of hydroxyquinoline in the combination product to the retardation of bacterial growth, although this demonstrated activity was insufficient to prevent ammonia formation. Other investigations in the submission showed that the antibacterial activity of the final formulation was directly related to another antimicrobial ingredient (boric acid) and that the activity of the hydroxyquinolines was shown to be diminished in the presence of the Zn^{++} ion from the zinc oxide in the formulation. A later submission (Ref. 3) from the same manufacturer stated that the hydroxyquinolines were included in the formula to provide the characteristic fragrance of the product in accordance with FDA's proposed rule for general conditions for use and labeling of inactive ingredients (April 12, 1977; 42 FR 19156). This submission also included revised labeling for this product which did not include any claims of antimicrobial activity.

In the "USAN and USP Dictionary of Drug Names" (Ref. 4), 8-hydroxyquinoline is designated as oxyquinoline and 8-hydroxyquinoline sulfate is designated as oxyquinoline sulfate. The Antimicrobial II Panel, the Vaginal Panel, and the Oral Cavity Panel classified the oxyquinolines as Category III for various OTC topical uses. The concentrations of the oxyquinolines reviewed by these panels were in the same range as the combination product labeled for diaper rash that was submitted to the Miscellaneous External Panel.

The Antimicrobial II Panel recommended that benzoxiquine, oxyquinoline, and oxyquinoline sulfate could be used alone or in combination to equal a total oxyquinoline concentration of 0.06 to 2.5 percent for the treatment of athletes foot, jock itch, and ringworm but placed these ingredients in Category III, concluding that there are insufficient data available to classify them as Category I for safety or effectiveness (47 FR 12540). The Vaginal Panel recommended that oxyquinoline citrate or oxyquinoline sulfate, used as a vaginal douche at a concentration of 2 percent for the relief of minor irritations of the vagina, be placed in Category III because the data are insufficient to prove safety or effectiveness for this use (48 FR 46715 to 46716). The Oral Cavity Panel reviewed the topical use of oxyquinoline sulfate at a 0.1-percent concentration in aqueous solution in the form of a rinse, gargle, or spray on the mucous membranes of the mouth and throat, not more than 3 or 4 times daily (47 FR 22881). The Panel concluded that the data available were insufficient to permit final classification of safety and effectiveness and placed the ingredient in Category III.

Based on the above and the historical usage of oxyquinoline as an active ingredient, the agency questions whether a total oxyquinoline concentration of 0.15 percent can be considered an inactive ingredient. A final determination of the status of oxyquinoline has not been made in any of the above-referenced rulemakings.

In the proposed rule concerning inactive ingredients (42 FR 19156 at 19157), the agency stated the following:

Various OTC drug panels have questioned whether an OTC drug may retain as an inactive ingredient an ingredient that was formerly listed as an active ingredient, but which was found not to be generally recognized as safe and effective (Category II) or to require additional testing (Category III). If these ingredients have been promoted by manufacturers for an extended time, there is a potential for misleading consumers if the general recognition of the safety and effectiveness issue is unresolved and the name of the ingredient is retained on the label or in the labeling with an unwarranted degree of prominence. The Commissioner believes this should not be permitted, and this proposal is intended to preclude the retention and redesignation of an active ingredient as an inactive ingredient unless it serves an acceptable function as an inactive ingredient. As a result, manufacturers of OTC drug products containing an ingredient in Category II or Category III shall, at the end of the time period permitted for marketing, or if found to require further testing before a determination as to general recognition of safety and effectiveness can be made for such ingredients, be required by the effective date either to reformulate the product to remove the ingredient or if it is retained in the product as an inactive ingredient, to establish that the ingredient fulfills the requirements for use as an inactive ingredient in the product.

This proposal states that "fragrances" are one of the acceptable categories for inactive ingredients (42 FR 19156 at 19160). The agency has no information that the oxyquinolines are necessary as fragrances, as defined in § 330.3(h) of the proposal, for use in OTC diaper rash drug products. The agency invites information and comments on (1) the use of oxyquinolines as fragrances in OTC diaper rash and related drug products and (2) the minimum concentration of oxyquinoline needed to achieve a fragrance effect.

Based on the above, the agency is classifying all oxyquinolines for use in diaper rash drug products in Category III for both safety and effectiveness, and is inviting the submission of additional information on their use as fragrances in such drug products.

References

(1) OTC Volume 160077.
(2) OTC Volume 160091.
(3) Comment No. C00163, Docket No. 75N-0183, Dockets Management Branch.
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J. Comment on P-Chloromercuriphenol.

15. One manufacturer submitted information to the Miscellaneous External Panel (Ref. 1) and the Antimicrobial II Panel (Ref. 2) for a product labeled as containing parachlormercuriphenol [1] in a hydrated base of lanolin with petrolatum, yellow wax, sodium borate, and aromatic oils with labeling that included claims for the treatment and prevention of diaper rash. The manufacturer subsequently notified the agency that the product is no longer marketed and withdrew the submissions (Ref. 3).

Although the Miscellaneous External Panel did not review this product specifically for its diaper rash claims, in another OTC drug rulemaking proceeding, that Panel classified all mercury compounds in Category II for topical antimicrobial use, citing problems associated with the safety of some and with the efficacy of all compounds (January 5, 1982; 47 FR 436). The Panel was unable to locate nor was it aware of any data demonstrating the safety and effectiveness of p-chloromercuriphenol when used as an OTC topical antimicrobial active ingredient and, without further discussion, the Panel classified it as Category II for this use (47 FR 436 at 438).

Toxicity from cutaneous mercury therapy has been reported since 1923 (Ref. 4). As noted by the Contraceptive Panel (45 FR 82014 at 82036), data indicated that at least two organic mercury compounds, phenylmercuric acetate and phenyl-mercury-dinaphtylmethane sulfonate, can be absorbed through the skin (Refs. 5 and 6). That Panel also noted that administration of calomel has caused specifically in infants a severe febrile (erythematous) disease known as acrodynia (pink disease) (Refs. 7, 8, and 9). While many cases of acrodynia have been attributed to orally ingested mercury in teething powders, the agency notes that there have been reports of acrodynia resulting from topical treatment of diaper rash with mercury containing ointments or diaper rinses (Refs. 10, 11, and 12).

In addition to concerns about mercury poisoning, the agency notes that p-chloromercuriphenol is a phenol derivative. Phenol (see comment 16 below) and phenol derivatives, such as hexachlorophene (see comment 10 above) and resorcinol (see comment 17 below), have also caused severe systemic toxicity, including death, in infants when applied externally. The agency believes that particular caution is needed when considering the use of any phenolic compound in infants.

There is a lack of toxicity data specific to p-chloromercuriphenol. However, in light of the above concerns about mercurials and phenolic compounds in general and in view of the two Panels' recommendations discussed above, the manufacturer's withdrawal of its submissions, and the fact that no other data were submitted on this ingredient, the agency is classifying p-chloromercuriphenol and all other mercury compounds in Category II for the treatment and prevention of diaper rash.

References

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(2) OTC Volume 070007.
(3) Letters from H. Jenkins, Creomulsion Company, to W.E. Gilbertson, FDA, dated February 3, 1987 and June 13, 1988, in OTC Volume 02DTFM, Docket No. 75N-183D, Dockets Management Branch.
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(5) Skerfving, S., "Organic Mercury Compounds—Relation Between Exposure and Effects," *in* "Mercury in the Environment," Edited by Friberg, L., and J. Vostal, The CRC Press, Cleveland, pp. 141-168, 1972.
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(12) Warkany, J., and D.M. Hubbard, "Mercury in the Urine of Children with Acrodynia," *The Lancet*, 1:829-830, 1948.

K. Comment on Phenol

16. One manufacturer submitted data (Refs. 1 and 2) to the Miscellaneous External Panel for two products, an ointment containing 0.16 percent phenol and a liquid containing 0.55 percent liquified phenol, in combination with various other active ingredients. The liquid preparation was labeled for "chafing" and "heat rashes and ordinary

[1] The agency has determined that the name "p-chloromercuriphenol" is the preferred name for this ingredient.

infant irritations" (Ref. 1). The ointment preparation was labeled "* * * helps prevent infection of * * * chafing, * * *," and "Relieves itching that accompanies many skin conditions such as common rashes, prickly heat, * * *" (Ref. 2). Although neither product was specifically labeled for use on infants or for diaper rash, the submitted data (Ref. 2) included a study on an ointment containing a combination of active ingredients that included 0.2 percent phenol in the management of diaper dermatitis in 20 infants, ages 5 weeks to 30 months. However, the study was a comparison of the total formulation compared to the total formulation with aloe active principle added. The study does not provide any information on the contribution of the phenol in the product to the results obtained.

Phenol has been reviewed for safety for topical, oral, and vaginal use in a number of OTC drug rulemakings. Phenol at concentrations greater than 1.5 percent (except in a special formulation with camphor) has been placed in Category II for safety in all rulemakings. Phenol at concentrations of 1.5 percent or less has received varying recommendations from different panels.

The Antimicrobial I Panel placed phenol at 1.5 percent or less in Category III for all antiseptic uses (September 13, 1974; 39 FR 33102 at 33133). That Panel was particularly concerned about the safety of using phenol in infants and recommended the warning: "Not to be used on infants under 6 months of age." The Panel noted that phenol is metabolized and eliminated from the body by glucuronide conjugation in the liver and there is a reported deficiency of metabolic conjugating mechanisms in infants. The Panel recommended that a toxicological evaluation of phenol should include studies to demonstrate safety in young animals deficient in these detoxification mechanisms and stated that because the liver is considered the major organ for conjugating, the effect of inadequate or impaired liver function on elimination and toxicity should also be determined.

The Panel was further concerned about the reports of local and systemic toxicity occurring after phenol-containing products had been applied over large areas of the body and covered with bandages. The Panel recommended that the use of phenol be restricted to small areas of the skin and that occlusive dressings, bandages, or diapers in any form should not be used. The Panel specifically concluded that phenol-containing preparations should not be used for the treatment of diaper rash, and recommended the following labeling: "Warning: Do not use for diaper rash or over large areas of the body or cover the treated area with a bandage or dressings," (39 FR 33133).

In the tentative final monograph for OTC antimicrobial drug products (January 6, 1978; 43 FR 1210), the Commissioner affirmed the conclusions of the Antimicrobial I Panel that phenol should not be used in infants until additional safety studies are conducted. The agency proposed a warning not to use phenol-containing products on infants under 6 months of age unless such studies are conducted (43 FR 1237 to 1238). The Commissioner also affirmed the Panel's conclusions that phenol-containing preparations should not be used for the treatment of diaper rash and should have a label stating "Warning: Do not use for diaper rash * * *." (43 FR 1238). The Commissioner further concluded that phenol may be used as an inactive ingredient for its aromatic characteristics in formulations in concentrations of less than 0.5 percent of phenol in a free state.

The Topical Analgesic Panel placed phenol 0.5 to 2 percent in Category I for use as an external analgesic (44 FR 69768 at 69832; December 4, 1979). However, in discussing the uses of topical drugs in infants (44 FR 69773 and 69774), the Panel stated: "The effects of occlusion from a diaper, lying on a waterproof mattress, wet clothing, or from body folds touching each other can cause disease and enhance cutaneous penetration of medicaments * * *. The Panel is concerned about the effects of a high local concentration of a drug on the integument itself under the occlusive conditions which exist in infants. Ingredients under occlusion may possibly be corrosive to the infant's skin. Biologic systems which metabolize and excrete drugs absorbed through the skin may not be fully developed in children less than 2 years of age." The Panel concluded that "to provide an added margin of safety, the ingredients reviewed below are not to be used for children under the age of 2 years except on the advice of a physician." Furthermore, in its evaluation of phenol (44 FR 69832 and 69833), the Panel stated that "dressings or compresses saturated with solutions of phenol, even though dilute, may cause sloughing, and are not recommended. Preparations containing 1 to 2 percent phenol should be applied only to the smallest area needing treatment and should not be bandaged to prevent severe skin irritation." The Panel recommended the following warning for products containing phenol: "Do not apply this product to extensive areas of the body or under compresses or bandages." The agency does not believe that the Panel's Category I evaluation of phenol as an external analgesic applies to use in diaper rash products which would be used on infants and children under 2 years of age, under occlusive diapers, and over extensive areas of the infant's body because all these conditions were specifically excluded by the Panel in its recommendation of phenol as safe for OTC use.

The Antimicrobial II Panel in its report on OTC antifungal drug products (March 23, 1982; 47 FR 12480) classified phenol in Category II for OTC topical use in the treatment of athlete's foot, jock itch and ringworm (47 FR 12518). The Panel stated that it received no data on the effect of dilute solutions of phenol on broken skin such as might be the case with athlete's foot, jock itch, or ringworm. The Panel also noted that in most reports of toxicity from dilute solutions of phenol bandaging was necessary to produce severe local changes. The Panel was concerned that using phenol in athlete's foot and jock itch would be similar to using it under a bandage because the affected areas would be covered by clothing. The Panel mentioned the specific lack of controlled studies evaluating (1) the absorption from small areas of application to either broken or intact skin, (2) the local effects of wound healing, and (3) the potential for hypersensitivity or idiosyncratic reaction. The Panel concluded that the use of phenol for athlete's foot, jock itch, and ringworm is outdated, irrational, and potentially dangerous. The agency considers these safety concerns about the topical use of phenol for jock itch in adults equally applicable to its use for diaper rash in infants.

The agency has considered the above three Panels' safety evaluations of topical phenol and other data, as discussed below, and concludes that phenol is not safe for use on infants for OTC diaper rash drug products. The specific safety concerns are (1) potential risks for local toxicity to skin when used under occlusive diapers, (2) potential for hypersensitivity reaction or topical overdose from skin absorption resulting in acute systemic toxicity especially in infants, and (3) potential for subacute percutaneous absorption from repeated use resulting in chronic systemic toxicity.

Accordingly, the agency has reassessed its prior conclusion of allowing the use of phenol as an inactive ingredient for its aromatic characteristics when such use would be in a diaper rash drug product. There is

an insufficient benefit to be gained from such use considering the potential risks to the infant. Therefore, phenol should not be used in any concentration as an active or inactive ingredient in a diaper rash drug product.

Based on the above, the agency is classifying phenol in Category II for safety as an ingredient in diaper rash drug products or for any labeling claims for similar uses in infants such as rash, prickly heat, heat rashes, chafing, or ordinary infant irritations.

The agency is aware that phenol 0.5 to 1.5 percent (and phenolate sodium 0.5 to 1.5 percent) has been proposed as Category I as an external analgesic in the tentative final monograph for OTC external analgesic drug products (48 FR 5867). Such products are indicated for the temporary relief of itching associated with minor skin irritations and rashes * * * and must bear the warning "Do not apply over large areas of the body or bandage," (48 FR 5869). Because of the agency's concerns that products containing phenol should not be used for diaper rash, the agency intends in the final monograph for OTC external analgesic drug products to expand the above warning to also state "Do not use for diaper rash."

References

(1) OTC Volume 160059.
(2) OTC Volume 160060.

L. Comment on Resorcinol

17. Submissions to the Miscellaneous External Panel (Ref. 1) and to the Antimicrobial I Panel (Ref. 2) were made by two manufacturers for products containing a combination of ingredients that included resorcinol. One product contained 2 percent resorcinol and the other contained 3 percent resorcinol. These products were labeled for the treatment of a number of skin conditions, including diaper rash. One submission (Ref. 1) stated that resorcinol was used in the product as a strong antiseptic. The submission also stated that resorcinol chemically resembled phenol in both formula and therapeutics, and the phenol coefficient of resorcinol against typhoid bacillis or staphylococcus is 0.4. The other submission (Ref. 2) stated that one of the medical uses of the product was as an antiseptic. No other data were submitted on the use of resorcinol.

Resorcinol has been reviewed for safety for topical use in five OTC drug rulemakings. In the **Federal Register** of December 3, 1982, the Miscellaneous External Panel concluded that resorcinol was safe for use on the scalp (for controlling seborrheic dermatitis or psoriasis) because of the limited size of the area and the thickness of the skin (47 FR 54646 at 54668). However, the Panel stated that resorcinol resembles phenol in its physiologic properties and, therefore, should not be used over large areas of the body or on thinner skin because enough drug can be absorbed through the skin to cause systemic poisoning. In the **Federal Register** of March 23, 1982, the Antimicrobial II Panel concluded that 2 percent resorcinol is safe for OTC topical use in the treatment of acne provided it has the following warning: "Apply to affected areas only. Do not use on broken skin or apply to large areas of the body," (47 FR 12430 at 12460). In the **Federal Register** of March 23, 1982, the same Antimicrobial II Panel concluded that the higher concentration of 10 percent resorcinol was not safe for OTC topical antifungal use in the treatment of athlete's foot, jock itch, and ringworm (47 FR 12480 at 12520).

In the **Federal Register** of December 4, 1979 (44 FR 69768), the Topical Analgesic Panel concluded that 0.5 to 3 percent resorcinol is safe for use as an external analgesic in adults and children 2 years of age and older but that the following warning was needed: "Do not apply this product to large areas of the body." The Panel noted that, although resorcinol is much less toxic than phenol, cases of poisoning have been reported, with some fatalities. The Panel cited an article by Cunningham (Ref. 3) who found eight cases (mostly in children) of resorcinol poisoning, six of which were fatal. (See 44 FR 69835.)

In the **Federal Register** of May 27, 1980, a majority of the Hemorrhoidal Panel found resorcinol safe for external use on adults in a 1 to 3 percent concentration as a keratolytic for the relief of itching (45 FR 35576 at 35665 and 35666). However, the Panel stated that the amount used must be limited because the toxicity of resorcinol is high. The Panel noted that resorcinol can be absorbed rapidly from mucous membranes, and that "Absorption has led to methemoglobinemia, exfoliative dermatitis and death in infants, * * *". The Panel recommended the warning "Do not use this product in children under 12 years of age except under the advice and supervision of a physician," (45 FR 35674). Further, a minority of the Panel concluded that the safety of 1 to 3 percent resorcinol for external use in OTC drug products remains to be established (45 FR 35666). This Panel also cited Cunningham (Ref. 3), who reviewed the literature and found seven cases of resorcinol poisoning from topical application in infants and young children. Six of the cited cases resulted in fatalities (Refs. 4 through 10). As discussed below, the cases frequently involved acute hemolytic anemia and methemoglobinemia.

Becker (Ref. 4) reported that a 42-day old infant suffering from extensive intertriginous eczema who was treated with one application of a 2 percent resorcinol/zinc paste reacted with vomiting, the passage of dark colored urine, and the development of an intense petechial skin eruption. In two days the infant's hemoglobin fell from 65 percent to 14 percent and the red blood cell count fell from 4,000,000 to 1,000,000 per cubic millimeter. The child died on the fifth day in spite of treatment with infusion of Ringer's solution and blood transfusion.

Nothen (Ref. 5) described poisoning in an 11-day-old infant suffering from pemphigus neonatorum who was found dead in bed some hours after the application of 3 percent resorcinol "vaseline."

Connerth (Ref. 6) reported on a 1½-year-old child with extensive eczema of the face and head who was first treated with a boric acid lotion and then for a few days with a 5-percent resorcinol zinc paste. The child became cyanosed and very ill. Hemoglobin fell to 45 percent, and there was associated hemoglobinemia and hemoglobinuria. The child died in convulsions.

Haenelt (Ref. 7) treated diaper rash in a 3-week-old infant with 5 percent resorcinol "vaseline." The infant was admitted to the hospital the next morning with severe cyanosis, burgundy colored urine, a hemoglobin of 53 percent, a red blood cell count of 2,900,000 per cubic millimeter, and bilirubin of 2.8 mg percent. The child deteriorated rapidly and died within 2 days. Death was due to methemoglobinemia.

Feigl (Ref. 8) described a 2-month-old infant suffering from generalized eczema who had been treated with resorcinol cream (concentration not stated). After 3 days, the child became desperately ill, developed convulsions, and died quickly.

Liebenam (Ref. 9) reported on a 36-day-old infant who had an intertriginous eczema diaper rash and was treated with a 20-percent resorcinol paste applied moderately thickly 5 to 6 times within 24 hours. The next day the child became gravely ill with intense general cyanosis. Hemoglobin fell to 65 percent and efforts to give blood intravenously were unsuccessful. The child died in convulsions 2 days after admission.

Kyrle (Ref. 10) reported on a 2-year-old boy with herpes tonsurans maculosus on the upper thighs treated with a 10-percent resorcinol lotion for 2

applications about 12 hours apart. After the second application, the boy's condition deteriorated rapidly. He became cyanosed with a weak irregular pulse and mild recurrent clonic fits. Within 12 hours, this condition improved but the boy developed a fever and severe dyspnea requiring oxygen therapy. He made a gradual recovery.

Cunningham (Ref. 3) discussed a case in which a 7-week-old infant was treated for diaper rash with an ointment containing 12.5 percent resorcinol. The ointment was applied on 4 occasions in less than a 24-hour period. After the fourth application, the mother noted that the infant shivered all over for about a minute. The infant's condition rapidly deteriorated during the day, and 6 hours later he was admitted to the hospital where the diagnosis of hemolytic anemia with hemoglobinuria was made. The infant developed a generalized papulo-squamous eruption which resulted in extensively desquamated skin over the body and a mass of thickened crusts on the scalp. Biochemical tests on the infant's blood serum and urine indicated that methemoglobin was also present. It was felt that the most likely cause was poisoning from a coal-tar derivative. Cunningham considered the diagnosis to be resorcinol poisoning. Urine tests for phenol derivatives were still positive 7 days after admission, but these phenol derivatives were not detected 13 days after admission. With blood transfusions and intravenous fluid, the infant made good progress and was discharged from the hospital after 27 days. However, it took more than 5 months for the infant's skin and scalp to fully heal.

Cunningham concluded that the above cases illustrate the danger of using resorcinol, even in the weakest lotion or ointment, topically on the skin of infants and young children. He stated that absorption may be intense and lethal where the skin is broken. He added that absorption may also occur and produce serious effects in sensitive subjects, even when the skin is almost intact. Cunningham concluded that resorcinol should not be used topically in the treatment of diaper rash, eczema, or other skin eruptions in childhood.

The agency notes that many of the infants in the above cases had diaper rash or eczema and that the concentration of resorcinol was similar to that found in marketed OTC diaper rash drug products. Based on the above incidences of poisoning resulting from the topical use of resorcinol on infants and children and the recommendations of several OTC drug advisory review panels, the agency considers resorcinol to be Category II for safety as an ingredient in diaper rash drug products.

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(5) Nothen, H., "Ueber Resorzinvergiftung bei auserer Anwendung," *Medizinische Klinik*, 4:901–902, 1908.
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(10) Kyrle, J., "Beitrag zur Kenntnis der Resorzinvergiftung bei auserer Applikation des Mittels," *Dermatologische Zeitschrift*, 22:505–510, 1915.

M. Comment on Sodium Propionate

18. One manufacturer made submissions to the Antimicrobial I Panel (Ref. 1), the Antimicrobial II Panel (Ref. 2), and the Miscellaneous External Panel (Ref. 3) for two products labeled as containing sodium propionate and water-soluble derivatives of chlorophyll. One product containing 5 percent sodium propionate and 0.0125 percent water-soluble derivatives of chlorophyll was formulated in an emollient ointment base and labeled as having antiseptic and fungistatic action in the treatment of a number of skin conditions, including diaper rash. The other product contained 2.3 g sodium propionate and 6 mg water-soluble derivatives of chlorophyll in individual powder packets for use as a wet dressing. The product was labeled as being antiseptic and fungistatic to relieve inflammation and itching of skin irritations, fungus infections, and minor burns, but did not have diaper rash claims. The submissions included a number of studies and review articles in support of the safe and effective use of sodium propionate and water-soluble chlorophyllin in the treatment of a variety of dermatologic conditions (including diaper rash). In the submissions, it was stated that the concentration of the water-soluble chlorophyllin in these products was much lower than that used for treatment purposes in other products. According to the submissions, this ingredient was only included in these products to deodorize the propionate content and thereby make the preparation acceptable to patients.

Based on the manufacturer's statements about the concentration and role of water-soluble derivatives of chlorophyll (chlorophyllin) in these products, the agency considers this ingredient to be inactive in these products. This position is consistent with the recommendation of the Antimicrobial II Panel that also evaluated a submission for these products and determined that chlorophyll is an inactive or pharmaceutically necessary ingredient. (See the advance notice of proposed rulemaking for OTC topical antifungal drug products at 47 FR 12485.)

Sodium propionate has been evaluated by two panels and found safe for OTC use at concentrations up to 20 percent. The Vaginal Panel concluded that the propionates (calcium or sodium salts) are safe in concentrations of up to 20 percent for OTC use in vaginal drug products which claim to relieve minor irritations of the vagina (48 FR 46694 at 46704). Substantial clinical data (Ref. 4) had been submitted on a product containing 10 percent sodium propionate and 10 percent calcium propionate that had been marketed for 30 years for prescription use in women with mycotic vulvovaginitis. The agency notes that this Panel stated that it specifically considered fetal and infant systemic safety when vaginal drug products are used by pregnant or nursing women (48 FR 46699).

The Antimicrobial II Panel concluded that propionic acid and its salts (sodium propionate and zinc propionate) are safe for a total combined propionate concentration of 20 percent for OTC topical antifungal use in the treatment of athlete's foot, jock itch, and ringworm (47 FR 12480 at 12547). This Panel noted that several submitted studies reported little local irritation from the topical use of propionates (Ref. 5). Some of these studies consisted of treatment regimens extending over several months with continuous use of propionates.

Propionic acid is one of several lower fatty acids occurring in sweat (Ref. 6). Peck and Russ (Ref. 7) explained, in their review of fatty acid therapy in general, that they were led to this treatment because their investigations had convinced them that human perspiration played a role as a protective mantle against skin infections. They further noted that, because fatty acids are more physiologic in their origin, they tend to be less

irritating and thus decrease the occurrence of local irritation and the development of dermatophytids which are often complicating sequela of the use of many antimicrobial chemicals. Sodium propionate was found to be less toxic in tissue culture tests than propionic acid (Ref. 8). Hara et al. (Ref. 9) reported that sodium and calcium propionates showed practically no toxicity when given to mice by oral administration in experiments of short duration. The propionates also showed no lowering of the growth curve when administered to rats by mouth in experiments of long duration, had no influence on hematological tests, and had no influence on both weights and volume of organs. No pathological changes upon histopathological examination and almost no detectable actions in general pharmacological tests were seen (Ref. 9).

Based on the above panel reviews and literature, it appears that there is no systemic toxicity hazard from topical absorption of sodium propionate. Nevertheless, the agency notes that very little data were submitted on topical use of this ingredient on infants. The agency concludes that before sodium propionate can be considered safe for OTC use in diaper rash drug products, studies should be conducted to determine the skin irritation and sensitization potential in infants when this ingredient is applied chronically under occlusion as occurs in the diaper area.

The agency is also concerned about the effect of sodium propionate on the skin flora under the occlusive conditions found in the diaper area when this ingredient is used chronically on infants and children. The agency believes that further in vivo bacteriological studies are needed, specifically in infants, to demonstrate the effect of the antibacterial activity of sodium propionate on the skin flora and whether this correlates with clinical improvements in diaper rash, and further whether long-term use of sodium propionate results in potentially harmful changes in the normal flora of the skin in the diaper area.

The manufacturer's submissions contained several articles (Refs. 10, 11, and 12) that discussed the use of products containing sodium proprionate as a therapeutic agent. Peck, Traub, and Spoor (Ref. 12) reported that in a small series of cases the combination of chlorophyllin-sodium propionate as a wet dressing and the use of an ointment containing 5 percent sodium propionate and 0.0125 percent chlorophyllin seemed to be an effective treatment for diaper rash. The wet dressing quickly controlled the acute symptoms, while the ointment acted as a healing and protective application and helped prevent recurrences. Edelson (Ref. 13) reported on use of the product in six patients with severely excoriated and macerated diaper eruptions: three made very prompt improvement using the wet dressing solution after each diaper change and as a regular cleansing agent with cotton; one patient improved moderately well, but after 1 week needed more active therapy; one infant showed no change in 4 days; and one infant cried bitterly with any watery application but did well with a paste application containing other ingredients. Noojin, Osment, and Taylor (Ref. 14) mention use of the product on 11 patients with infantile eczema, but no information is provided as to whether the condition was diaper rash. Other authors (Refs. 13 and 14) have shown that in in vitro studies sodium propionate inhibits the growth of bacteria including *S. aureus*, beta hemalytic streptococcus, *E. coli*, and *P. aeruginosa*.

The agency finds the submitted information inadequate to establish the safety and effectiveness of sodium propionate for antiseptic or antifungal use in diaper rash drug products. The number of infants with diaper rash who were studied was very limited. None of the information is from a well-controlled clinical study. Further, the Antimicrobial II Panel found the data it reviewed insufficient to establish the effectiveness of propionic acid and its salts (sodium propionate and zinc propionate) as an antifungal in the treatment of athlete's foot, jock itch, and ringworm. That Panel stated that "In vitro antifungal data suggest that propionates are bacteriostatic and fungistatic," but that the "* * * data is quite old and uses zone of inhibition and contact-time testing so that only general conclusions can be drawn." (See 47 FR 12547.) No additional data were submitted in response to the advance notice of proposed rulemaking. Propionates remain classified in Category III in the tentative final monograph for OTC antifungal drug products (54 FR 51136 at 51156).

The agency concludes that the available data are inadequate to support the antimicrobial or antifungal use of sodium propionate in diaper rash drug products and classifies the ingredient as Category III for both safety and effectiveness.

References

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(2) OTC Volume 070146.
(3) OTC Volume 160105.
(4) OTC Volumes 110027 and 070031.
(5) OTC Volume 070032.
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N. Comment on Triclosan

19. Several submissions to the Antimicrobial I Panel and comments to the rulemaking for OTC topical antimicrobial drug products were made by the manufacturer of a medicated powder product containing triclosan (0.1 percent), corn starch, zinc oxide, and kaolin as active ingredients (Refs. 1 and 2). The product was labeled for use in a number of skin conditions, including diaper rash and chafing. It was also labeled as "helps prevent urine irritation" and "kills millions of diaper rash germs." The submissions included animal and human safety data pertaining to triclosan, reports of in vitro antimicrobial efficacy of triclosan, and a report of in vitro antimicrobial efficacy of the finished product. The manufacturer contended that the product has excellent activity against urea-splitting organisms which are contributing factors in diaper rash. The

manufacturer of triclosan also submitted safety and efficacy data (Ref. 3) that included reports of antibacterial activity and ammonia inhibition of diapers rinsed with a fabric softener containing triclosan. However, no labeling for any commercial product for diaper rinse use was provided.

The Antimicrobial I Panel (39 FR 33102 at 33127) reviewed triclosan for use in topically applied antimicrobial products and classified it in Category III for both safety and effectiveness. The Panel expressed concerns about its chronic use and about its use on infants under 6 months of age. The Panel noted that glucuronide conjugation is "a major route of elimination of triclosan from the body" and that "this mechanism may be deficient in young animals and human infants." The Panel also pointed out the need for safety data relevant to long-term use and recommended a label warning "Do not use this product on infants under 6 months of age," for products containing triclosan.

Subsequent to the publication of the Panel's report, the manufacturer of triclosan submitted validation reports and raw data from a 2-year chronic oral toxicity study in rats by Industrial Bio-Test Laboratories (IBT) (Ref. 4). With regard to safety, the agency evaluated the validation reports to support long-term use of the ingredient and advised the manufacturer of triclosan that the 2-year chronic oral toxicity studies were invalid because of numerous problems. The agency's detailed comments and evaluations on the data are on file in the Dockets Management Branch (Ref. 5).

The manufacturer subsequently stated its intent to no longer rely on the earlier 2-year chronic oral toxicity IBT study (Ref. 6). Recently, the manufacturer submitted a final report from a new 2-year chronic oral toxicity study in rats which the agency is evaluating (Ref. 7).

The same manufacturer also submitted safety data pertaining to neonate rhesus monkeys bathed in soap containing 0.1 percent triclosan (Ref. 8). The agency has evaluated the data and determined that the bathing study in neonate rhesus monkeys contributes little to support the safe use of triclosan for human infants because of the low exposure dose of 0.1 percent triclosan. Although the study demonstrated that neonate monkeys, like human neonates, can metabolize triclosan in more than one way and would not be disposed to liver damage, even at the low exposure level, tissue levels approached 2 parts per million. A study using a greater area of application, more frequent bathing, and a higher concentration of triclosan would be more supportive to establish safe use in diaper rash drug products.

Another study on absorption, metabolism, and excretion in newborn and adult rhesus monkeys indicated that both handle triclosan similarly, the sulfate ester predominating. Sulfate conjugation is better developed in infants than glucuronide conjugation. However, this does not imply that there is no problem. An infant has the same problem as an adult—persistence due to the sulfate ester. The agency is also concerned about the use of a phenolic compound in infants and cannot make a final risk assessment without adequate data. The agency considers the benefit-to-risk ratio to be unacceptably small if there is any potential risk at all.

Pending completion of the agency's evaluation of the new 2-year study (Ref. 7) and the submission of additional data, as discussed above, triclosan remains classified in Category III for safety for long-term use in infants. Further, the agency is aware that the Environmental Protection Agency (EPA) denied a request by the manufacturer of triclosan to remove the label warning on fabric softeners containing triclosan that states "Do not use for baby diaper laundry," (Ref. 9). This remains EPA's current position (Ref. 10).

Jungermann and Taber (Ref. 11) briefly discussed a study on 151 infants to test for mildness of two bath soaps: (1) A test soap containing 0.1 percent triclosan, 1 percent hexachlorophene, and 1 percent triclocarban; and (2) a nonmedicated soap (Ivory). The protocol was an 8-week blind cross-over where one group of infants is bathed exclusively with one of the soaps for 4 weeks and then with the other soap for another 4 weeks. The condition of the skin in general and of the diaper area in particular was examined each week. Nurses bathing the infants used the same soap for their own washing. Apparently only 51 infants remained in the hospital long enough to complete the trial of 4 weeks with each soap. The other infants were bathed with each soap for varying (unspecified) shorter periods. The authors stated that there was no evidence of primary irritation or allergic contact dermatitis from use of either soap but did not give any further details.

The agency notes that very little data were submitted on the topical use of triclosan on infants, particularly for diaper rash. The agency has determined that studies should be conducted to determine the skin irritation and sensitization potential in infants when this ingredient is applied chronically under occlusion as occurs in the diaper area.

The submissions from manufacturers of the ingredient and the product include in vitro tests of the antimicrobial effectiveness of triclosan. These tests include studies on the inhibition of ammonia production in diapers rinsed with a fabric softener containing triclosan. The results indicate that triclosan is bacteriostatic against a wide range of gram negative and gram positive species, as well as many fungi.

The agency has evaluated the role of bacteria in causing or aggravating diaper rash (see comments 1 and 2 above) and has concluded that more data are needed regarding the intended effect of antimicrobial treatment of diaper rash. The agency has concerns about the safety and efficacy of continuously and routinely using antimicrobial drugs in the diaper area just for the purpose of generally reducing the microflora count. The agency believes that further in vivo bacteriological studies are needed, specifically in infants. These studies need to demonstrate the effect of the antibacterial activity of triclosan on the skin flora and show whether this correlates with clinical improvements in diaper rash. They also need to determine whether long-term use of triclosan results in potentially harmful changes in the normal flora of the skin in the diaper area.

The data submitted for triclosan do not adequately address these concerns. Most of the studies were performed in vitro or involved the use by adults of triclosan formulated in antimicrobial soap. The one report of triclosan-containing soap used in infants pertained to the evaluation of the mildness of the soap to infant skin (Ref. 11) and did not address the issue of bacterial involvement in diaper dermatitis or demonstrate clinical effectiveness. More information, as discussed above, is needed before triclosan can be placed in Category I for the prevention or treatment of diaper rash. Accordingly, the agency is classifying triclosan for use in diaper rash drug products in Category III for both safety and effectiveness.

References

(1) OTC Volumes 020077, 020078, and 020079.

(2) Comment Nos. C00114 and SUP020, Docket No. 75N-0183, Dockets Management Branch.

(3) OTC Volumes 020033, 020034, 020035, 020036, 020037, 020038, 020039, and 020040.

(4) "Two-Year Chronic Oral Toxicity Study With FAT 80' 023/A in Albino Rats," Comment No. C00109, Volume 1, Appendix E, and Comment No. C00139, Volumes 1 through 8, Docket No. 75N-0183, Dockets Management Branch.

(5) Letter from W.E. Gilbertson, FDA, to R. Bernegger, Ciba-Geigy Corp., coded LET028/

ANS, Docket No. 75N–0183, Dockets Management Branch.

(6) Memorandum of Meeting between FDA Staff and Representatives of Ciba-Geigy Corp., September 6, 1983, Comment No. MM0007, Docket No. 75N–0183, Dockets Management Branch.

(7) "FAT 80' 023 2-Year Oral Administration in Rats," Volumes XLI, XLII, and XLIII and "Determination of FAT 80' 023 in Blood and Tissue Samples Taken During a Two-Year Chronic Oral Toxicity/Oncogenicity Study in Albino Rats," Volume XLIV, Comment No. RPT002, Docket No. 75N–0183, Dockets Management Branch.

(8) Comment No. C00109, Docket No. 75N–0183, Dockets Management Branch.

(9) Letter from A.E. Castillo, EPA, to J. LoMenzo, Ciba-Geigy Corp., dated September 21, 1982, in OTC Volume 02DTFM, Docket No. 75N–183D, Dockets Management Branch.

(10) Memorandum of telephone conversation between W. Campbell, EPA, and L. Geismar, FDA, dated January 6, 1988, in OTC Volume 02DTFM, Docket No. 75N–183D, Dockets Management Branch.

(11) Jungermann, E., and D. Taber, "A New Broad Spectrum Antibacterial Soap: 1. General Properties," *Journal of the American Oil Chemists' Society*, 48:318–323, 1971.

O. Comment on Testing

20. One comment submitted a number of recommendations for criteria for evaluating diaper rash ingredients and included protocols for two clinical studies to demonstrate both treatment and prevention of diaper rash. Although the comment directed most of its statements to skin protectant drug products, it also recommended that diaper rash combination products containing skin protectant and nonskin protectant active ingredients meet the criteria for skin protectants as well as the criteria established under the appropriate monographs for the other ingredients, e.g., antimicrobials, antifungals, or external analgesics.

This comment is discussed in detail in comment 34 of the tentative final monograph for OTC skin protectant diaper rash drug products, published elsewhere in this issue of the Federal Register. The agency states in that comment that testing guidelines for skin protectant diaper rash ingredients would not be included in that document and any interested person wanting advice on Category III testing should communicate directly with the agency. Similarly, testing guidelines for antimicrobial diaper rash ingredients are not being included in this document. (See also part III. paragraph A.2. below—*Testing of Category II and Category III conditions.*)

II. The Agency's Evaluation of the Submissions

Of the ingredients listed in the Miscellaneous External Panel's statement, the following are currently included in the rulemaking for OTC topical antimicrobial drug products: alkyldimethyl benzylammonium chloride,[1] benzethonium chloride, chloroxylenol, hexachlorophene, methylbenzethonium chloride, p-chloromercuriphenol, phenol and phenylmercuric nitrate. The agency has reviewed the submissions to the Miscellaneous External Panel and determined that 21 submissions (Ref. 1) relate to products containing these ingredients for use in the treatment of diaper rash.

A number of submissions (Ref. 2) to the Antimicrobial I and II Panels included products containing antimicrobial ingredients (benzalkonium chloride, boric acid, calcium undecylenate, chloroxylenol, hexachlorophene, methylbenzethonium chloride, p-chloromercuriphenol, resorcinol, sodium propionate (with chlorophyll derivatives) and triclosan) labeled for use in the treatment and prevention of diaper rash. Some of these ingredients (sodium propionate (with chlorophyll derivatives) and triclosan) were not included in the Miscellaneous External Panel's statement. In addition, a number of comments (Ref. 3) received in response to the tentative final monograph for OTC topical antimicrobial drug products (January 6, 1978; 43 FR 1210) were relevant to the use of these antimicrobial ingredients in diaper rash. The agency has also included these submissions and comments in this rulemaking.

References

(1) OTC Volumes 160025, 160027, 160040, 160042, 160059, 160060, 160077, 160091, 160105, 160221, 160235, 160236, 160242, 160243, 160244, 160245, 160246, 160247, 160320, 160357, and 160427.

(2) OTC Volumes 020001, 020008, 020016, 020023, 020026, 020028, 020030, 020033, 020034, 020035, 020036, 020037, 020038, 020039, 020040, 020044, 020046, 020051, 020065, 020077, 020078, 020079, 020088, 020146, 020188, 070007, 070021, 070029, 070031, 070032, 070074, 070075, 070076, 070077, 070078, 070079, and 070146.

(3) Comments No. RPT005, RPT00006, C00048, C00061, C00109, C00114, C00116, C00163, SUP013, SUP018, SUP020, SUP028, Docket No. 75N–0183, Dockets Management Branch.

[1] The agency has determined that the name "benzalkonium chloride" is the preferred name for this ingredient.

III. The Agency's Tentative Conclusions and Adoption of the Panel's Statement

A. Summary of Ingredient Categories and Testing of Category II and Category III Conditions

1. Summary of Ingredient Categories

Although the Panel discussed the use of antimicrobial ingredients for the treatment of diaper rash, it did not classify any ingredients. All ingredients in marketed products submitted to the Panel or ingredients that appeared in the call-for-data notice were simply listed in the Panel's statement on OTC drug products for the treatment of diaper rash (47 FR 39406). The Panel recommended that several of the antimicrobial ingredients included in this list be referred to the rulemaking for OTC topical antimicrobial drug products and recommended that the other ingredients be referred to the rulemaking(s) that FDA considered most appropriate. In publishing the Panel's statement, the agency requested public comment from interested persons.

The agency has reviewed all claimed active ingredients submitted to the Miscellaneous External Panel, the recommendations of the Antimicrobial I Panel (39 FR 33102), the tentative final monograph on OTC topical antimicrobial drug products (43 FR 1210), and other data and information available at this time. Based upon this information, the agency is proposing the following categorization of antimicrobial active ingredients for the treatment and prevention of diaper rash:

Ingredient	Category
Benzalkonium chloride	III
Benzethonium chloride	III
Boric acid	II
Calcium undecylenate	III
Chloroxylenol	III
Hexachlorophene	II
Methylbenzethonium chloride	III
Oxyquinoline	III
P-Chloromercuriphenol	II
Phenol	II
Resorcinol	II
Sodium propionate	III
Triclosan	III

2. Testing of Category II and Category III Conditions

The agency is not proposing specific testing guidelines in this document. Interested persons may communicate with the agency about the submission of data and information to demonstrate the safety or effectiveness of any antimicrobial ingredient or condition included in the review by following the procedures outlined in the agency's

policy statement published in the Federal Register of September 29, 1981 (46 FR 47740) and clarified April 1, 1983 (48 FR 14050). That policy statement includes procedures for the submission and review of proposed protocols, agency meetings with industry or other interested persons, and agency communications on submitted test data and other information.

B. Summary of Agency's Changes

FDA has considered the comments and other relevant information and concludes that it will tentatively adopt the substance of the Panel's statement. The agency has proposed labeling in this tentative final monograph in the event that new data are submitted to establish "monograph conditions" for OTC topical antimicrobial active ingredients for the treatment or prevention of diaper rash. This labeling is similar to that proposed for OTC skin protectant diaper rash drug products, elsewhere in this issue of the Federal Register, with some minor modifications to reflect the topical antimicrobial action of these products.

In the event that no new data are submitted to the agency during the alloted 12-month new data period or if the submitted data are not sufficient to establish "monograph conditions" for OTC topical antimicrobial drug products for the treatment or prevention of diaper rash, the agency will consider such products to be new drugs under section 201(p) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 321), for which applications approved under section 505 of the act (21 U.S.C. 355) and 21 CFR part 314 are required for marketing. If this occurs, upon the effective date of that portion of the final rule for OTC topical antimicrobial drug products that applies to OTC diaper rash drug products, any OTC drug products containing topical antimicrobial active ingredients and labeled for the treatment and/or prevention of diaper rash that are initially introduced or initially delivered for introduction into interstate commerce would be regarded as unapproved new drugs and subject to regulatory action. Manufacturers are encouraged to comply voluntarily with the proposed rule at the earliest possible date.

The agency has examined the economic consequences of this proposed rulemaking in conjunction with other rules resulting from the OTC drug review. In a notice published in the Federal Register of February 8, 1983 (48 FR 5806), the agency announced the availability of an assessment of these economic impacts. The assessment determined that the combined impacts of all the rules resulting from the OTC drug review do not constitute a major rule according to the criteria established by Executive Order 12291. The agency therefore concludes that no one of these rules, including this proposed rule for OTC topical antimicrobial drug products for the treatment or prevention of diaper rash, is a major rule.

The economic assessment also concluded that the overall OTC drug review was not likely to have a significant economic impact on a substantial number of small entities as defined in the Regulatory Flexibility Act (Pub. L. 96–354). That assessment included a discretionary regulatory flexibility analysis in the event that an individual rule might impose an unusual or disproportionate impact on small entities. However, this particular rulemaking for OTC topical antimicrobial drug products for the treatment or prevention of diaper rash is not expected to pose such an impact on small businesses. Therefore, the agency certifies that this proposed rule, if implemented, will not have a significant economic impact on a substantial number of small entities.

The agency invites public comment regarding any substantial or significant economic impact that this rulemaking would have on OTC topical antimicrobial drug products for the treatment or prevention of diaper rash. Types of impact may include, but are not limited to, costs associated with product testing, relabeling, repackaging, or reformulating. Comments regarding the impact of this rulemaking on OTC topical antimicrobial drug products for the treatment or prevention of diaper rash should be accompanied by appropriate documentation. Because the agency has not previously invited specific comment on the economic impact of the OTC drug review on topical antimicrobial drug products for the treatment or prevention of diaper rash, a period of 180 days from the date of publication of this proposed rulemaking in the Federal Register will be provided for comments on this subject to be developed and submitted. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency invited public comment in the advance notice of proposed rulemaking regarding any impact that this rulemaking would have on OTC topical antimicrobial drug products used for the treatment of diaper rash. No comments on economic impacts were received. Any comments on the agency's initial determination of the economic consequences of this proposed rulemaking should be submitted by December 17, 1990. The agency will evaluate any comments and supporting data that are received and will reassess the economic impact of this rulemaking in the preamble to the final rule.

The agency has determined under 21 CFR 25.24(c)(6) that this action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Interested persons may, on or before December 17, 1990, submit to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments, objections, or requests for oral hearing before the Commissioner on the proposed rulemaking. A request for an oral hearing must specify points to be covered and time requested. Written comments on the agency's economic impact determination may be submitted on or before December 17, 1990. Three copies of all comments, objections, and requests are to be submitted, except that individuals may submit one copy. Comments, objections, and requests are to be identified with the docket number found in brackets in the heading of this document and may be accompanied by a supporting memorandum or brief. Comments, objections, and requests may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday. Any scheduled oral hearing will be announced in the Federal Register.

Interested persons, on or before June 20, 1991, may also submit in writing new data demonstrating the safety and effectiveness of those conditions not classified in Category I. Written comments on the new data may be submitted on or before August 20, 1991. These dates are consistent with the time periods specified in the agency's final rule revising the procedural regulations for reviewing and classifying OTC drugs, published in the Federal Register of September 29, 1981 (46 FR 47730). Three copies of all data and comments on the data are to be submitted, except that individuals may submit one copy, and all data and comments are to be identified with the docket number found in brackets in the heading of this document. Data and comments should be addressed to the Dockets Management Branch (HFA–305) (address above). Received data and comments may also be seen in the office

above between 9 a.m. and 4 p.m., Monday through Friday.

In establishing a final monograph for OTC topical antimicrobial drug products, the agency will ordinarily consider only data submitted prior to the closing of the administrative record on August 20, 1991. Data submitted after the closing of the administrative record will be reviewed by the agency only after a final monograph for OTC topical antimicrobial drug products is published in the **Federal Register**, unless the Commissioner finds good cause has been shown that warrants earlier consideration.

List of Subjects in 21 CFR Part 333

Diaper rash drug products, Labeling, Over-the-counter drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Administrative Procedure Act, it is proposed that subchapter D of chapter I of title 21 of the Code of Federal Regulations be amended in part 333 as follows:

PART 333—TOPICAL ANTIMICROBIAL DRUG PRODUCTS FOR OVER-THE-COUNTER HUMAN USE

1. In part 333 by adding a new subpart F as follows:

Subpart F—Diaper Rash Drug Products

Sec.

Authority: Secs. 201, 501, 502, 503, 505, 510, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 351, 352, 353, 355, 360, 371).

Subpart F—Diaper Rash Drug Products

§ 333.501 Scope.

(a) An over-the-counter diaper rash drug product in a form suitable for topical administration is generally recognized as safe and effective and is not misbranded if it meets each of the conditions in this subpart and each of the general conditions established in § 330.1 of this chapter.

(b) References in this subpart to regulatory sections of the Code of Federal Regulations are to chapter I of title 21 unless otherwise noted.

§ 333.503 Definitions.

As used in this subpart:

Diaper rash or diaper dermatitis. An inflammatory skin condition in the diaper area (perineum, buttocks, lower abdomen, and inner thighs) caused by one or more of the following factors: moisture, occlusion, chafing, continued contact with urine or feces or both, or mechanical or chemical irritation. Mild conditions appear as simple erythema. More severe conditions include papules, vesicles, oozing, and ulceration.

§ 333.510 Diaper rash active ingredients. [Reserved]

§ 333.550 Labeling of diaper rash drug products.

(a) *Statement of identity.* The labeling of the product contains the established name of the drug, if any, and identifies the product as an "antiseptic diaper rash" (insert dosage form, e.g., "ointment," "cream," or "powder").

(b) *Indications.* The labeling of the product states under the heading "Indications," the following: "Helps" (select one or more of the following: "reduce," "guard against," or "protect against") (select one of the following: "infection" or "skin infection") "associated with diaper rash." Other truthful and nonmisleading statements, describing only the indications for use that have been established and listed in paragraph (b) of this section, may also be used, as provided in § 330.1(c)(2) of this chapter, subject to the provisions of section 502 of the Federal Food, Drug, and Cosmetic Act (the act) relating to misbranding and the prohibition in section 301(d) of the act against the introduction or delivery for introduction into interstate commerce of unapproved new drugs in violation of section 505(a) of the act.

(c) *Warnings.* The labeling of the product contains the following warnings under the heading "Warnings":

(1) "For external use only."

(2) "Avoid contact with the eyes."

(3) "If condition worsens or does not improve within 7 days, consult a physician."

(4) *For powder products only.* "Do not use on broken skin. Keep powder away from child's face to avoid inhalation which can cause breathing problems."

(d) *Directions.* The labeling of the product contains the following statements, as appropriate, under the heading "Directions:"

(1) *For all products.* "Change wet and soiled diapers promptly, cleanse the diaper area, and allow to dry. Apply" (select one of the following: "ointment," "cream," "powder, or "product") "liberally as often as necessary, with each diaper change, especially at bedtime or anytime when exposure to wet diapers may be prolonged."

(2) *For powder products only.* "Apply powder close to the body away from child's face. Carefully shake the powder into the diaper or into the hand and apply to diaper area."

Dated: April 24, 1990.

James S. Benson,

Acting Commissioner of Food and Drugs.

[FR Doc. 90-13851 Filed 6-19-90; 8:45 am]

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June 20, 1990

Part VI

Department of Labor

Pension and Welfare Benefits Administration

29 CFR Parts 2560 and 2570

Interim and Proposed Regulations Relating to Civil Penalties Under ERISA Section 502(l)

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2570

RIN 1210-AA37

Interim Regulation Relating to Civil Penalties Under ERISA Section 502(l)

AGENCY: Pension and Welfare Benefits Administration, Department of Labor.

ACTION: Interim rule.

SUMMARY: This document contains an interim regulation that describes the procedures relating to the assessment of civil penalties under section 502(l) of the Employee Retirement Income Security Act of 1974, as amended (ERISA or the Act). A separate document which contains a proposed regulation defining certain terms under ERISA section 502(l) is also being published today.

Section 502(l) requires the Secretary of Labor (the Secretary) to assess a civil penalty against a fiduciary who breaches a fiduciary responsibility under, or commits any other violation of, part 4 of title I of ERISA or any other person who knowingly participates in such breach or violation. The regulation sets forth the procedures for the assessment of penalties under ERISA section502(l) and for petitioning the Secretary to exercise his or her discretion to waive or reduce the mandated assessment.

DATES: This interim regulation is effective June 20, 1990, and will apply to any assessment made by the Secretary after June 20, 1990 based on any breach of fiduciary responsibility under, or other violation of, part 4 of title I of ERISA occurring on or after December 19, 1989. Written comments concerning this interim rule must be received by the Department of Labor (the Department) on or before August 20, 1990.

ADDRESSES: Interested persons are invited to submit written comments concerning this interim rule to: Pension and Welfare Benefits Administration, room N-5671, U.S. Department of Labor, 200 Constitution Ave., NW, Washington, DC 20210. Attention: Interim section 502(l) Civil Penalty Rule. All submissions will be open to public inspection at the Public Documents Room, Pension and Welfare Benefits Administration, U.S. Department of Labor, room N-5507, 200 Constitution Ave., NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Vicki Shteir-Dunn, Plan Benefits Security Division, Office of the Solicitor, (202) 523-9596, and David Lurie, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, (202) 523-8671.

SUPPLEMENTARY INFORMATION: Section 502(l) requires the Secretary to assess a civil penalty against a fiduciary who breaches a fiduciary responsibility under, or commits a violation of, part 4 of title I of ERISA or any other person who knowingly participates in such breach or violation.[1] The penalty under section 502(l) is equal to 20 percent of the "applicable recovery amount" paid pursuant to any settlement agreement with the Secretary or ordered by a court to be paid in a judicial proceeding instituted by the Secretary under section 502(a)(2) or (a)(5). The Secretary may, in the Secretary's sole discretion, waive or reduce the penalty if the Secretary determines in writing that either: (1) The fiduciary or other person acted reasonably and in good faith, or (2) it is reasonable to expect that the fiduciary or other person will not be able to restore all losses to the plan or any participant or beneficiary of such plan without severe financial hardship unless such waiver or reduction is granted. The penalty imposed on a fiduciary or other person with respect to any transaction shall be reduced by the amount of any penalty or tax imposed on such fiduciary or other person with respect to such transaction under ERISA section 502(i) or section 4975 of the Internal Revenue Code of 1986 (the Code). A separate notice of proposed rulemaking dealing with the definition of the terms "applicable recovery amount", "breach of fiduciary responsibility", "violation", "continuing violation", "settlement agreement", and "court order" is also being published today.

In general, the interim regulation addresses the procedures under which a penalty will be assessed (§ 2570.83), when an assessed penalty must be paid (§ 2570.84, and the circumstances pursuant to which the Secretary may waive or reduce a penalty (§§ 2570.85 and 2570.86). Specifically, subsequent to the payment of the applicable recovery amount pursuant to either a settlement agreement or a court order, the Secretary [2] will serve on the person liable for making such payment a notice of assessment of civil penalty equal to 20 percent of the applicable recovery amount. The "notice of assessment" is defined generally as any document, however designated, issued by the Secretary which contains a specified assessment, in monetary terms of a civil penalty under ERISA section 502(l). A "notice of assessment" will also contain a brief factual description of the violation for which the assessment is being made, the identity of the person being assessed, and the amount of the assessment and the basis for assessing that particular person that particular penalty amount.

Service of the notice of assessment will be made in one of three ways: (1) By delivering a copy to the person being assessed; if the person is a partnership, any partner; if the person is a corporation, association, exchange, or other entity or organization, any officer of such entity; if the person is an employee benefit plan, a trustee of such plan; or any attorney representing the person in this matter; (2) by leaving a copy at the principal office, place of business, or residence of such individual, partner, officer, trustee, or attorney; or (3) by mailing a copy to the last known address of such individual, partner, officer, trustee, or attorney. If service is accomplished by certified mail, service is complete upon mailing. If done by regular mail, service is complete upon receipt by the addressee.

A person being assessed a penalty will have 60 days from the service of the notice of assessment to pay the assessed amount. Subject to any tolling of this 60-day payment period during the consideration of a waiver or reduction petition described below, the notice of assessment will become a final agency action (within the meaning of 5 U.S.C. 704) on the first day following the 60-day period. At any time prior to the expiration of that 60-day period, a person may request a conference with the Secretary to discuss the calculation of the assessment or may petition the Secretary to waive or reduce the assessed penalty. In the case of a request to discuss the calculation of the assessment, the Secretary will schedule such conference as soon as is administratively feasible. The 60-day payment period will not, however, be tolled upon such request.[3]

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[1] Section 502(l) was added to ERISA by section 2101 of the Omnibus Budget Reconciliation Act of 1989.

[2] In this regard, the Secretary has established the Pension and Welfare Benefits Administration within the Department for the purpose of carrying out most of the Secretary's responsibilities under ERISA. See, Secretary's Order 1-87, 52 FR 13139 (April 21, 1987). Thus, the Department contemplates that the duties assigned to the Secretary under this procedural regulation will in fact be discharged by the Assistant Secretary for Pension and Welfare Benefits or the appropriate Area Director or Deputy Area Director.

[3] If, based on a conference, the Secretary determines that a factual mistake has occurred which reduces the amount of the penalty already paid, a refund of that mistaken overpayment will be made as soon as is administratively feasible. See § 2570.87 concerning the revision of assessments.

At any time prior to the expiration of the 60-day payment period, a person may also petition the Secretary to waive or reduce the assessed penalty on one of two grounds: (1) That the person acted reasonably and in good faith in engaging in the breach or violation; [4] or (2) the person will not be able to restore all losses to the plan or any participant or beneficiary of such plan without severe financial hardship unless such waiver or reduction is granted.[5] A petition to waive or reduce must be in writing and contain the following information: (1) The name of the petitioner; (2) a detailed description of the breach or violation which is the subject of the penalty; (3) a detailed recitation of the facts which support one, or both, of the bases for waiver or reduction described above, accompanied by underlying documentation supporting such factual allegations; and (4) a declaration, signed and dated by the petitioner, which states that under penalty of perjury, the petitioner is making true and correct representations to the best of his or her knowledge and belief.

If the petition for waiver or reduction of penalty is submitted during the 60 day payment period, the payment period for the penalty in question will be tolled pending Departmental consideration of the petition. During such consideration, the petitioner is also entitled to one conference with the Secretary. The Secretary may, however, in his or her sole discretion, schedule or hold additional conferences with the petitioner concerning the factual allegations contained in the petition. Once the Secretary has made a determination with regard to the petition, the petitioner will be served a written determination briefly informing him of the Secretary's decision and the grounds for that decision. Such determination is solely within the Secretary's discretion and is a final, non-reviewable order. In those situations where the Secretary concludes that no waiver or reduction shall be granted, the payment period for the penalty in question, if previously initiated, will resume as of the date of service of the determination on the petitioner.[6]

Any penalty assessed under ERISA section 502(l) and this rule on a person with regard to any particular transaction will be reduced by the amount of any penalty or tax imposed on such person with respect to such transaction under ERISA section 502(i) and section 4975 of the Code. Prior to such a reduction, the person being assessed must provide proof to the Department of his or her payment of the penalty or tax and the amount of such payment. Submissions of proof of other penalty or tax assessments will not toll the 60-day payment period, if previously initiated.

If, based on information gained through a conference, waiver or reduction petition, or submission of proof of other penalty or tax payment, the Department determines that a previously issued notice of assessment should be revised, the Department shall issue a revised notice of assessment to the person being assessed, and that person will be obligated to pay the revised assessed penalty within the relevant 60-day period (as determined by the applicable procedure in §§ 2570.84, 2570.85, or 2570.86), and, where necessary, any excess penalty payment will be refunded as soon as administratively feasible. The revised notice of assessment will revoke any previously issued notice with regard to the transaction in question, and will become a final order (within the meaning of 5 U.S.C. 704) the later of the first day following the 60-day payment period or the date of its service on the person being assessed, pursuant to the service procedures described in § 2570.83(b).

Because this rule deals solely with agency procedures and is not a substantive rule, the Administrative Procedure Act (APA) at 5 U.S.C. 553(b)(3)(A) permits its publication without notice or opportunity for comment, and 5 U.S.C. 553(d) permits this rule to become effective immediately. Moreover, due to the statutory mandate requiring the Secretary to assess penalties under ERISA section 502(l) based on any breach or violation occurring on or after December 19, 1989, as well as the need to continue unabated the Department's ERISA enforcement efforts (e.g., settlement agreements through voluntary compliance), the Department is promulgating this rule effective immediately. As promulgated, the rule will apply to assessments made by the Secretary after June 20, 1990, based on any breaches or violations occurring on or after December 19, 1989. Published today is a separate notice of proposed rulemaking defining, among other terms, what constitutes a violation for purposes of ERISA section 502(l).

Regulatory Flexibility Act Statement

The Regulatory Flexibility Act imposes certain requirements with respect to rules which would have a significant impact on a substantial number of small entities. A "rule" under the Regulatory Flexibility Act is one for which a general notice of proposed rulemaking is required under section 553(b) of the Administrative Procedure Act. Under section 553(b) of the Administrative Procedure Act, a general notice of proposed rulemaking is not required for rules of agency organization, procedure or practice. Thus, such rules are excluded from the definition of "rule" under the Regulatory Flexibility Act. Since this procedural regulation is a rule of agency procedure or practice, it is not subject to the requirements of the Regulatory Flexibility Act.

Executive Order 12291

The Department has determined that this regulatory action would not constitute a "major rule" as that term is used in Executive Order 12291 because the action does not result in: An annual effect on the economy of $100 million; a major increase in costs or prices for consumers, individual industries, government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Paperwork Reduction Act

The Paperwork Reduction Act mandates that agencies provide data with respect to information collection requirements which may be imposed by certain regulatory actions. Section 3518(c)(1)(B) of the Paperwork Reduction Act provides that the requirements of the Act do not apply to

[4] As a general matter, in determining whether a fiduciary or knowing participant acted reasonably and in good faith, the Department will examine the decisionmaking process with respect to the transaction in question to determine whether it was designed to adequately safeguard the interests of the participants and beneficiaries of the plan. In absence of such a decisionmaking process, actual favorable investment return to the plan will not provide a sufficient showing that a person acted reasonably and in good faith with regard to a particular transaction. See ERISA Technical Release Number 85–1 for general guidelines concerning the Department's previously-articulated views concerning evidence of good faith.

[5] A person may make these arguments not only with regard to actual losses to the plan, but also with regard to any disgorgement of profits gained through the relevant breach or violation or amounts necessary for transfer to the plan in order to correct the relevant breach or violation.

[6] Service of the petition determination will be achieved in a similar fashion to that of the notice of assessment. Thus, in calculating the resumption of the 60-day payment period, refer to the previous discussion concerning service of the notice of assessment for purposes of determining when service is achieved. See also paragraph 2570.87 concerning the procedure for the revision of previously issued notices of assessments.

administrative actions involving specific individuals or entities. The Department has determined that the administrative adjudications which would be conducted pursuant to the procedures contained in this regulation fall within the scope of this exemption from the Paperwork Reduction Act.

Statutory Authority

This Interim Rule is adopted pursuant to the authority contained in section 505 of ERISA (Pub. L. 93–406, 88 Stat. 892, 894; 29 U.S.C. 1135).

List of Subjects in 29 CFR Part 2570

Administrative practice and procedure, Employee benefit plans, Employee Retirement Income Security Act, Party in interest, Law enforcement, Pensions, Pension and Welfare Benefits Administration, Prohibited transactions.

Interim Rule

In view of the foregoing the Department is amending part 2570 of chapter XXV of title 29 of the Code of Federal Regulations as follows:

PART 2570—[AMENDED]

By adding in the appropriate place in part 2570 the following new subpart D:

Subpart D—Procedure for the Assessment of Civil Penalties Under ERISA Section 502(1)

Sec.

Subpart D—Procedure for the Assessment of Civil Penalties Under ERISA Section 502(l)

§ 2570.80 Scope of rules.

The rules of practice set forth in this subpart are applicable to "502(l) civil penalty proceedings" (as defined in § 2570.82 of this subpart) under section 502(l) of the Employee Retirement Income Security Act of 1974 (ERISA or the Act). Refer to 29 CFR 2560.5021 for the definition of the relevant terms of ERISA section 502(l).

§ 2570.81 In general.

Section 502(l) of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) requires the Secretary of Labor to assess a civil penalty against a fiduciary who breaches a fiduciary responsibility under, or commits any other violation of, part 4 of Title I of ERISA or any other person who knowingly participates in such breach or violation. The penalty under section 502(l) is equal to 20 percent of the "applicable recovery amount" paid pursuant to any settlement agreement with the Secretary or ordered by a court to be paid in a judicial proceeding instituted by the Secretary under section 502 (a)(2) or (a)(5). The Secretary may, in the Secretary's sole discretion, waive or reduce the penalty if the Secretary determines in writing that:

(a) The fiduciary or other person acted reasonably and in good faith, or

(b) It is reasonable to expect that the fiduciary or other person will not be able to restore all losses to the plan or any participant or beneficiary of such plan without severe financial hardship unless such waiver or reduction is granted.

The penalty imposed on a fiduciary or other person with respect to any transaction shall be reduced by the amount of any penalty or tax imposed on such fiduciary or other person with respect to such transaction under section 502(i) or section 4975 of the Internal Revenue Code of 1986 (the Code).

§ 2570.82 Definitions.

For purposes of this section:

(a) *502(l) civil penalty proceedings* means an adjudicatory proceeding relating to the assessment of a civil penalty provided in section 502(l) of ERISA;

(b) *Notice of assessment* means any document, however designated, issued by the Secretary which contains a specified assessment, in monetary terms, of a civil penalty under ERISA section 502(l). A "notice of assessment" will contain a brief factual description of the violation for which the assessment is being made, the identity of the person being assessed, and the amount of the assessment and the basis for assessing that particular person that particular penalty amount;

(c) *Person* includes an individual, partnership, corporation, employee benefit plan, association, exchange or other entity or organization;

(d) *Petition* means a written request, made by a person, for a waiver or reduction of the civil penalty described herein; and

(e) *Secretary* means the Secretary of Labor and includes, pursuant to any delegation of authority by the Secretary, the Assistant Secretary for Pension and Welfare Benefits, Area Directors for Pension and Welfare Benefits, or Deputy Area Directors for Pension and Welfare Benefits.

§ 2570.83 Assessment of civil penalty.

(a) Except as described in §§ 2570.85 and 2570.86 below, subsequent to the payment of the applicable recovery amount pursuant to either a settlement agreement or a court order, the Secretary shall serve on the person liable for making such payment a notice of assessment of civil penalty equal to 20 percent of the applicable recovery amount.

(b) Service of such notice shall be made either:

(1) By delivering a copy to the person being assessed; if the person is an individual, to the individual; if the person is a partnership, to any partner; if the person is a corporation, association, exchange, or other entity or organization, to any officer of such entity; if the person is an employee benefit plan, to a trustee of such plan; or to any attorney representing any such person;

(2) By leaving a copy at the principal office, place of business, or residence of such individual, partner, officer, trustee, or attorney; or

(3) By mailing a copy to the last known address of such individual, partner, officer, trustee, or attorney.

If service is accomplished by certified mail, service is complete upon mailing. If done by regular mail, service is complete upon receipt by the addressee.

§ 2570.84 Payment of civil penalty.

(a) The civil penalty must be paid within 60 days of service of the notice of assessment.

(b) At any time prior to the expiration of the payment period for the assessed penalty, any person who has committed, or knowingly participated in, a breach or violation, or has been alleged by the Secretary to have so committed or participated, may submit a written request for a conference with the Secretary to discuss the calculation of the assessed penalty. A person will be entitled under this section to one such conference per assessment. If such written request is submitted during the 60 day payment period described in subparagraph (a), such a request will not toll the running of that payment period.

(c) The notice of assessment will become a final order (within the meaning of 5 U.S.C. 704) on the first day following the 60 day payment period, subject to any tolling caused by a petition to waive or reduce described in paragraph 2570.85.

§ 2570.85 Waiver or reduction of civil penalty.

(a) At any time prior to the expiration of the payment period for the assessed penalty, any person who has committed, or knowingly participated in, a breach or violation, or has been alleged by the Secretary to have so committed or participated, may petition the Secretary to waive or reduce the penalty under this section on the basis that:

(1) The person acted reasonably and in good faith in engaging in the breach or violation; or

(2) The person will not be able to restore all losses to the plan or participant or beneficiary of such plan without severe financial hardship unless such waiver or reduction is granted.

(b) All petitions for waiver or reduction shall be in writing and contain the following information:

(1) The name of the petitioner(s);

(2) A detailed description of the breach or violation which is the subject of the penalty;

(3) A detailed recitation of the facts which support one, or both, of the bases for waiver or reduction described in § 2570.85(a) of this part, accompanied by underlying documentation supporting such factual allegations;

(4) A declaration, signed and dated by the petitioner(s), in the following form: Under penalty of perjury, I declare that, to the best of my knowledge and belief, the representations made in this petition are true and correct.

(c) If a petition for waiver or reduction is submitted during the 60 day payment period described in § 2570.84(a) above, the payment period for the penalty in question will be tolled pending Departmental consideration of the petition. During such consideration, the applicant is entitled to one conference with the Secretary, but the Secretary, in his or her sole discretion, may schedule or hold additional conferences with the petitioner concerning the factual allegations contained in the petition.

(d) Based solely on his or her discretion, the Secretary will determine whether to grant such a waiver or reduction. Pursuant to the procedure described in § 2570.83(b), the petitioner will be served with a written determination informing him or her of the Secretary's decision. Such written determination shall briefly state the grounds for the Secretary's decision, and shall be final and non-reviewable. In the case of a determination not to waive, the payment period for the penalty in question, if previously initiated, will resume as of the date of service of the Secretary's written determination.

§ 2570.86 Reduction of Penalty by Other Penalty Assessments.

The penalty assessed on a person pursuant to this section with respect to any transaction shall be reduced by the amount of any penalty or tax imposed on such person with respect to such transaction under ERISA section 502(i) and section 4975 of the Code. Prior to a reduction of penalty under this paragraph, the person being assessed must provide proof to the Department of the payment of the penalty or tax and the amount of that payment. Submissions of proof of other penalty or tax assessments will not toll the 60 day payment period, if previously initiated.

§ 2570.87 Revision of assessment.

If, based on the procedures described in §§ 2570.84, 2570.85, or 2570.86, the assessed penalty amount is revised, the person being assessed will receive a revised notice of assessment and will be obligated to pay the revised assessed penalty within the relevant 60 day payment period (as determined by the applicable procedure in §§ 2570.84, 2570.85, or 2570.86), and, if necessary, any excess penalty payment will be refunded as soon as administratively feasible. The revised notice of assessment will revoke any previously issued notice of assessment with regard to the transaction in question and will become a final order (within the meaning of 5 U.S.C. 704) the later of the first day following the 60 day payment period or the date of its service on the person being assessed, pursuant to the service procedures described in § 2570.83(b).

§ 2570.88 Effective Date.

This section is effective June 20, 1990 and shall apply to assessments under section 502(l) made by the Secretary after June 20, 1990 based on any breach or violation occurring on or after December 19, 1989.

Signed at Washington, DC, this 11th day of June, 1990.

David George Ball,

Assistant Secretary for Pension and Welfare Benefits, U.S. Department of Labor.

[FR Doc. 90-14177 Filed 6-19-90; 8:45 am]

BILLING CODE 4510-29-M

DEPARTMENT OF LABOR

Pension and Welfare Benefits Administration

29 CFR Part 2560

RIN 1210-AA37

Proposed Regulation Relating to Civil Penalties Under Erisa Section 502(l)

AGENCY: Pension and Welfare Benefits Administration, Department of Labor.

ACTION: Notice of proposed rulemaking.

SUMMARY: This document contains a proposed regulation that defines the terms "applicable recovery amount", "breach of fiduciary responsibility or violation", and "settlement agreement or court order" under section 502(l) of the Employee Retirement Income Security Act of 1974 (ERISA or the Act). Section 502(l) requires the Secretary of Labor (the Secretary) to assess a civil penalty against a fiduciary who breaches a fiduciary responsibility under, or commits any other violation of part 4 of, title I of ERISA or any other person who knowingly participates in such breach or violation. This proposed regulation would clarify the manner in which the Secretary will assess the civil penalties described in section 502(l) and enable the Department to carry out its mandate under that section. A separate document which contains an interim regulation describing the procedures the Department will follow in assessing the penalties contemplated by section 502(l) is also being published today.

DATES: Written comments concerning the proposed regulation must be received by August 20, 1990. If adopted, the regulation would be effective with respect to section 502(l) assessments made after 30 days from the date of its publication as a final regulation.

ADDRESSES: Interested persons are invited to submit written comments concerning this proposed regulation to: Pension and Welfare Benefits Administration, Room N-5671, U.S. Department of Labor, 200 Constitution Ave., NW., Washington, DC 20210. Attention: Proposed Section 502(l) Regulation. All submissions will be open to public inspection at the Public Documents Room, Pension and Welfare Benefits Administration, U.S. Department of Labor, Room N-5507, 200 Constitution Ave., NW., Washington, DC 20210.

FOR FURTHER INFORMATION CONTACT: Vicki Shteir-Dunn, Plan Benefits Secretary Division, Office of the Solicitor, (202) 523-9596, and David Lurie, Office of Regulations and Interpretations, Pension and Welfare Benefits Administration, (202) 523-8671.

SUPPLEMENTARY INFORMATION: Section 502(l) requires the Secretary to assess a civil penalty against a fiduciary who breaches a fiduciary responsibility under, or commits a violation of, part 4 of title I of ERISA or any other person who knowingly participates in such breach or violation.[1] The penalty under section 502(l) is equal to 20 percent of the "applicable recovery amount" paid pursuant to any settlement agreement with the Secretary or ordered by a court to be paid in a judicial proceeding instituted by the Secretary under section 502(a)(2) or (a)(5). The Secretary may, in the Secretary's sole discretion, waive or reduce the penalty if the Secretary determines in writing that either: (1) The fiduciary or other person acted reasonably and in good faith, or (2) it is reasonable to expect that the fiduciary or other person will not be able to restore all losses to the plan or any participant or beneficiary of such plan without severe financial hardship unless such waiver or reduction is granted. The penalty assessed on a fiduciary or other person with respect to any transaction shall be reduced by the amount or any penalty or tax imposed on such fiduciary or other person with respect to such transaction under ERISA section 502(i) or section 4975 of the Internal Revenue Code of 1986 (the Code). A separate interim regulation describing the procedures the Department will follow in assessing penalties under section 502(l) is also being published today.

This proposed regulation would provide: (1) A definition of the term "applicable recovery amount" with regard to a settlement agreement or court order to which the civil penalty in ERISA section 502(l) will be applied; and (2) a definition of the terms "breach of fiduciary responsibility", "violation", "settlement agreement", and "court order" as utilized in section 502(l) in order to determine those instances in which the civil penalty provisions of that section are triggered.

Applicable Recovery Amount

Section 502(l) states that a civil penalty equaling 20 percent of the "applicable recovery amount" shall be assessed by the Secretary [2] in certain circumstances. Based on the statutory language of section 502(l)(2), the Department generally defines the term "applicable recovery amount" to mean any amount which is recovered on behalf of an employee benefit plan or any participant or beneficiary of such a plan from a fiduciary with respect to a breach of fiduciary responsibility under, or other violation of, part 4 of title I of ERISA which such fiduciary committed or from a person who knowingly participated in such breach or violation. Such amount may be recovered pursuant to either a settlement agreement with the Secretary or a court order resulting from a judicial proceeding instituted by the Secretary under section 502(a)(2) or (a)(5).

As required by section 502(l), the Department proposes to assess penalties under section 502(l) on fiduciaries who commit breaches of fiduciary responsibility under, or other violations of, part 4 of title I or other persons who knowingly participate in such breaches or violations. In this regard, the Department will make the assessment only after the applicable recovery amount is paid to the plan,[3] and will calculate the penalty assessement with regard to a breaching fiduciary or a knowing participant solely on the amount paid by such breaching person.[4] Because section 502(l) defines the term as any amount recovered from a fiduciary or knowing participant with respect to a breach or violation, the "applicable recovery amount" paid by such a breaching fiduciary or knowing participant will include amounts paid to the plan by such person which represent loss suffered by the plan, disgorged profits, and amounts necessary to achieve correction.

Section 2101 of the Omnibus Budget Reconciliation Act of 1989, which amended ERISA to include section 502(l), states that this civil penalty provision shall apply to any breach of

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[1] Section 502(l) was added to ERISA by section 2101 of the Omnibus Budget Reconciliation Act of 1989 (OBRA 1989) (Pub. L. 101-239, 103 Stat. 2106).

[2] In this regard, the Secretary has established the Pension and Welfare Benefits Administration within the Department for the purpose of carrying out most of the Secretary's responsibilities under ERISA. See, Secretary's Order 1-87, 52 FR 13139 (April 21, 1987). Thus, the Department contemplates that the duties assigned to the Secretary under section 502(l) will in fact be discharged by the Assistant Secretary for Pension and Welfare Benefits or one of his or her delegates.

[3] In those cases where it is agreed that the breaching fiduciary or knowing participant will pay its applicable recovery amount in a series of payments to the plan, the Department may assess a section 502(l) penalty after each payment received by the plan or may wait until the full applicable recovery amount has been paid prior to assessing a single section 502(l) penalty.

[4] Thus, in the case of a prohibited transaction with party in interest A cause by fiduciary F in which A is neither a fiduciary nor a knowing participant, the twenty percent penalty assessment on F will not be based on any amount that A repays to the plan as correction. Also, A will not be liable for a civil penalty under section 502(l) or any portion of F's penalty under such section.

fiduciary responsibility under, or other violation of, part 4 of title I occurring on or after December 19, 1989.[5] Thus, the Secretary is mandated to assess civil penalties not only on those breaches or violations which are initiated or entered into subsequent to December 18, 1989, but also on those breaches and violations which, although entered into prior to December 19, 1989, continue as breaches or violations after that date.[6] In this regard, the Department proposes a separate definition of what constitutes the "applicable recovery amount" in the case of a "continuing violation" which, although entered into prior to December 19, 1989, continues beyond that date. In order to equitably assess this penalty in accordance with the effective date of section 502(l), the Department proposes to define the term "applicable recovery amount" for a "continuing violation" as the total amount recovered pursuant to either a settlement agreement or court order reduced by any portion of that amount attributable to any portion of the violation which occurred prior to December 19, 1989. Thus, any loss, profit, or correction amount which is paid to a plan, any participant or beneficiary of a plan, or any legal representative(s) of a plan or plan participant or beneficiary, based on a violation which was initiated prior to, but continued beyond, December 19, 1989, must be examined to determine whether any portion of that amount accrued and, hence, is paid to the plan, plan participant, or plan beneficiary, because of that portion of the violation which occurred prior to December 19, 1989. If such is the case, the "applicable recovery amount" will reflect that fact. The regulation contains two examples illustrating the calculation of the "applicable recovery amount" in the context of such a "continuing violation".

Breach of Fiduciary Responsibility or Violation

Section 502(l) states that a civil penalty shall be assessed against a fiduciary who commits a breach of fiduciary responsibility under (or other violation of) part 4 of title I of ERISA, or any other person who knowingly participates in such a breach or violation. Thus, the Department defines a "breach of fiduciary responsibility" or "violation" to mean any act which contravenes a provisions of part 4 of title I of ERISA. As so defined, a section 502(l) civil penalty will be assessed on applicable recovery amounts paid due to not only violations of the prohibited transactions rules of ERISA section 406 but also breaches of fiduciary responsibility under ERISA sections 403 and 404.[7]

A "violation" includes both transactions which occur at one particular time, e.g., a prohibited sale, and transactions which by their very nature occur for extended periods of time and may be discontinued or terminated at any time during their existence, e.g., a prohibited loan. The statutory language of section 502(l) encompasses *all* violations, thereby, including both types of violations described above. Thus, the Department proposes to define the term "violation" to include "continuing violations", defining such term as a violation which by its very nature occurs for a period of time and may be discontinued at any time during its existence or duration. As previously discussed, this concept of "continuing violations" is relevant to the assessment of civil penalties under section 502(l) primarily due to the nature of the effective date of this statutory provisions.[8]

Settlement Agreements and Court Orders

Section 502(l)(2) defines the term "applicable recovery amount" as any amount which is recovered from a fiduciary or knowing participant with respect to a breach or violation of part 4 of title I pursuant to either a "settlement agreement" with the Secretary or "court order" following a judicial proceeding instituted by the Secretary. The Department proposes to define the term "settlement agreement" as an agreement between the Secretary and a person who the Secretary alleges to have committed a breach of fiduciary responsibility under, or other violation of any provision of, part 4 of title I of ERISA pursuant to which a claim for such breach or violation is to be released by the Secretary in return for cash or other property being tendered to a plan, the participants and beneficiaries of a plan, or the legal representative(s) of a plan or plan participants and beneficiaries. Hence, the provisions of section 502(l) will apply to voluntary compliance agreements between the Secretary and breaching fiduciaries and other persons who knowingly participate in such breaches. For purposes of ERISA section 502(l), the Department defines the term "court order" as a judicial decree which either awards monetary damages or provides equitable relief.[9]

Effective Date of Regulation

Pursuant to the requirements of the Administrative Procedure Act at 5 U.S.C. 553(b), the Department is publishing this notice of proposed rulemaking for comment and will promulgate this rule in final form subsequent to such comment period, effective 30 days after its publication in final form. The Department takes this opportunity to alert all interested parties that prior to the effective date of this rule in final form, the Department adopts the provisions of this notice of proposed rulemaking as a general statement of policy.[10] Hence, prior to the effective date of this rule in final form, it is the intention of the Department to assess civil penalties under ERISA section 502(l) utilizing the definitions proposed herein. However, any person who is subject to an assessment of a civil penalty under section 502(l) in the interim may exercise his right to a conference (as described in the Interim Procedural Regulation relating to section 502(l) published herein today) [11] to raise any issues concerning this general statement of policy and that particular assessment.

Regulatory Flexibility Act

The Department has determined that this regulatory action will not have a significant impact on a substantial number of small entities. The primary purpose of the regulation is to deter fiduciaries from engaging in a breach of fiduciary responsibility or a violation of ERISA, or the knowing participation of any other person in such breach or violation. The Department estimates

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[5] ERISA section 502(l) became effective on the date of enactment of OBRA 1989—December 19, 1989.

[6] For discussion as to what constitutes a "continuing violation", see the discussion below.

[7] By so saying, the Department does not imply that a breach or violation of any other provision of part 4 would not result in an assessment of penalty under section 502(l). *Any* breach or violation of *any* provisions of part 4 which results in an "applicable recovery amount", as defined herein, will trigger the mandated civil penalty assessment. For example, an amount recovered from a fiduciary based on the liability provisions of ERISA section 405 will fall within the definitional parameters of the section 502(l) term "applicable recovery amount" and, as such, will trigger a civil penalty assessment.

[8] See the previous discussion concerning the nature of the effective date of section 502(l), the definition of the term "applicable recovery amount", and the method of calculating such amount for the purpose of assessing a section 502(l) penalty in a continuing violation context.

[9] If, however, the equitable relief awarded does not involve the transfer to the plan of money or property, no civil penalty may be assessed pursuant to section 502(l).

[10] 5 U.S.C. 553(b)(3)(A) exempts general statements of policy from the general requirement that notice and opportunity for comment be given on proposed rulemaking. 5 U.S.C. 553(d)(2) exempts statements of policy from the general 30 day delayed effective date requirement for rulemaking.

[11] See 2570.84(b) of the Interim Procedural Regulation.

that from the date of enactment, the number of individual assessments under this section will continually increase, leveling out to approximately 840 assessments per year by fiscal year 1994. Some of these penalties will involve fiduciaries and knowing participants in fiduciary breaches with respect to small plans, or other small entities; however, given the selective nature of the burden imposed by this regulation, the Department believes that the regulation will not have a significant impact on small entities generally.

Executive Order 12291

The Department has determined that this regulatory action would not constitute a "major rule" as that term is used in Executive Order 12291 because the action does not result in: an annual effect on the economy of $100 million; a major increase in costs or prices for consumers, individual industries, government agencies, or geographic regions; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

Paperwork Reduction Act

The proposed regulation defining terms which relate to the assessment of penalties under ERISA section 502(l) does not contain any new information collection requirements and does not modify any existing requirements. Thus, it is not subject to section 3504(h) of the Paperwork Reduction Act, 44 U.S.C. 3504(h).

Authority

This proposed regulation would be adopted pursuant to the authority contained in section 505 of ERISA (Pub. L. 93-406, 88 Stat. 892, 894; 29 U.S.C. 1135).

List of Subjects in 29 CFR Part 2560

Claims, Employee benefit plans, Employee Retirement Income Security Act, Law enforcement, Pensions

Proposed Rule

In view of the foregoing, the Department proposes to amend part 2560 of chapter XXV of title 29 of the Code of Federal Regulations as set forth below:

PART 2560—[AMENDED]

By adding in the appropriate place in part 2560 a new 2560.502l–1 as follows:

2560.502l–1 Civil Penalties Under Section 502(l).

(a) *Scope.* The definitions set forth in this section are applicable to "502(l) civil penalty proceedings" (as defined in 29 CFR 2570.81) under section 502(l) of the Employee Retirement Income Security Act of 1974 (ERISA or the Act). Refer to 29 CFR 2570.80 through 2570.88 for the rules of procedure for the assessment of civil penalties under ERISA section 502(l).

(b) *In general.* Section 502(l) of the Employee Retirement Income Security Act of 1974 (ERISA or the Act) requires the Secretary of Labor to assess a civil penalty against a fiduciary who breaches a fiduciary responsibility under, or commits a violation of, part 4 of title I of ERISA or any other person who knowingly participates in such breach or violation. The penalty under section 502(l) is equal to 20 percent of the "applicable recovery amount" paid pursuant to any settlement agreement with the Secretary or ordered by a court to be paid in a judicial proceeding instituted by the Secretary under section 502 (a)(2) or (a)(5). The Secretary may, in the Secretary's sole discretion, waive or reduce the penalty if the Secretary determines in writing that:

(1) The fiduciary or other person acted reasonably and in good faith, or

(2) It is reasonable to expect that the fiduciary or other person will not be able to restore all losses to the plan or any participant or beneficiary of such plan without severe financial hardship unless such waiver or reduction is granted.

The penalty imposed on a fiduciary or other person with respect to any transaction shall be reduced by the amount of any penalty or tax imposed on such fiduciary or other person with respect to such transaction under section 502(i) or section 4975 of the Internal Revenue Code of 1986 (the Code).

(c) *Applicable recovery amount.* Section 502(l) states that a civil penalty equaling 20 percent of the "applicable recovery amount" shall be assessed by the Secretary in certain circumstances. The term "applicable recovery amount" means any amount which is recovered from a fiduciary by an employee benefit plan, any participant or beneficiary of such plan, or any legal representative of such with respect to a breach of fiduciary responsibility under, or other violation of, part 4 of title I of ERISA which such fiduciary committed or from a person who knowingly participated in such breach or violation. Such amount may be recovered pursuant to either a settlement agreement with the Secretary or a court order resulting from a judicial proceeding instituted by the Secretary under section 502(a)(2) or (a)(5). The "applicable recovery amount" with regard to a continuing violation will equal the total amount recovered pursuant to either a settlement agreement or court order reduced by any portion of that amount attributable to any portion of the violation which occurred prior to December 19, 1989.

Example 1: Fiduciary F causes Plan A to make F a prohibited loan, initiated on December 19, 1988, and extending to December 19, 1991. In December of 1991, F enters into a settlement agreement with the Department to pay A $3 million in correction of such transaction and to disgorge to A $300,000 in profits F earned from the proceeds of the prohibited loan. F earned all of the profits to be disgorged prior to December 19, 1989. In determining the "applicable recovery amount", the Department will reduce the $3,300,000 amount paid to the plan by the $300,000 of disgorged profits earned on the proceeds of the prohibited loan prior to the effective date of section 502(l). The Department will calculate the penalty amount based on the "applicable recovery amount" of $3 million, the amount reflecting the value of the extension of credit (i.e., the violation) occurring within the effective period of section 502(l).

Example 2: Fiduciary F causes Plan A to make party in interest B (who is not a fiduciary or knowing participant with regard to this transaction) a below-market prohibited loan of $3 million, initiated on December 19, 1988, and extending to December 19, 1991. In June of 1992, after B has paid back the loan according to its terms, F enters into a settlement agreement with the Department, agreeing to pay A $60,000 in lost interest income ($20,000 of which represents the additional interest A should have earned on its investment prior to December 19, 1989). In determining the "applicable recovery amount", the Department will reduce the $60,000 amount paid to A by $20,000 (the amount of the additional interest which should have accrued prior to December 19, 1989, and, thus, represents a loss to A due to that portion of the violation occurring prior to the effective date of section 502(l)). On these facts, the Department will assess the penalty on the "applicable recovery amount" of $40,000.

(d) *Breach of fiduciary responsibility or other violation.* Section 502(l) states that a civil penalty shall be assessed against a fiduciary who commits a breach of fiduciary responsibility under (or other violation of) part 4 of title I of ERISA, or any other person who knowingly participates in such a breach or violation. The term "breach of fiduciary responsibility" or "violation" means any act which contravenes a provision of part 4 of title I of ERISA, including those acts which constitute continuing violations. In this context, a "continuing violation" is a violation which by its very nature occurs for a period of time and may be discontinued at any time during its existence or duration. For example, ERISA section

406(a)(1)(B) prohibits a fiduciary from causing a plan to engage in a transaction, if he knows or should know that such transaction constitutes a direct or indirect extension of credit between the plan and a party in interest. Because a loan is a type of transaction which exists for a period of time, it may be discontinued at any time from its initiation unitl its maturity. Thus, a loan or extension of credit which constitutes a violation as defined in this section is a "continuing violation".

(e) *Settlement agreements and court orders.* Section 502(l) states that the applicable recovery amount is any amount which is recovered with respect to a breach or violation described in paragraph (d) pursuant to either a "settlement agreement" with the Secretary or a "court order" in a judicial proceeding instituted by the Secretary. A "settlement agreement" is an agreement between the Secretary and a person who the Secretary alleges to have committed a breach of fiduciary responsibility or violation of any provision of part 4 of title I of ERISA pursuant to which a claim for such breach or violation is to be released in return for cash or other property being tendered to a plan, any participant and beneficiary of a plan, or the legal representative(s) of a plan or plan participants and beneficiaries. A "court order" is a judicial decree which either awards monetary damages or provides equitable relief.

(f) *Effective Date.* This section is effective (the date 30 days after the publication of this regulation in final form) and shall apply to any assessment under section 502(l) made thereafter with regard to any breach or violation occurring on or after December 19, 1989.

Signed at Washington, DC, this 11th day of June, 1990.

David George Ball,

Assistant Secretary for Pension and Welfare Benefits, U.S. Department of Labor.

[FR Doc. 90-14178 Filed 6-19-90; 8:45 am]

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federal register

Wednesday
June 20, 1990

Part VII

The President

Executive Order 12717—Revoking Executive Order No. 12691

Federal Register
Vol. 55, No. 119
Wednesday, June 20, 1990

Presidential Documents

Title 3—

The President

Executive Order 12717 of June 18, 1990

Revoking Executive Order No. 12691

By the authority vested in me as President by the Constitution and laws of the United States of America, and since the President's Advisory Committee on the Points of Light Initiative Foundation ("Committee") has completed its tasks, it is hereby ordered that Executive Order No. 12691, which established the Committee, is revoked.

THE WHITE HOUSE,
June 18, 1990.

[FR Doc. 90-14502
Filed 6-19-90; 11:56 am]
Billing code 3195-01-M

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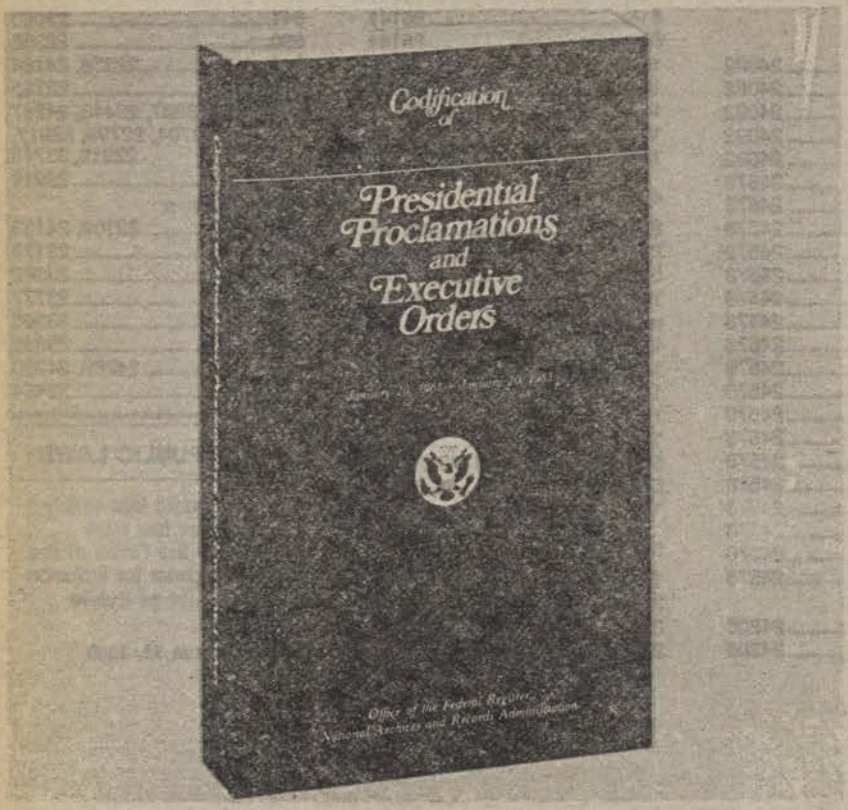

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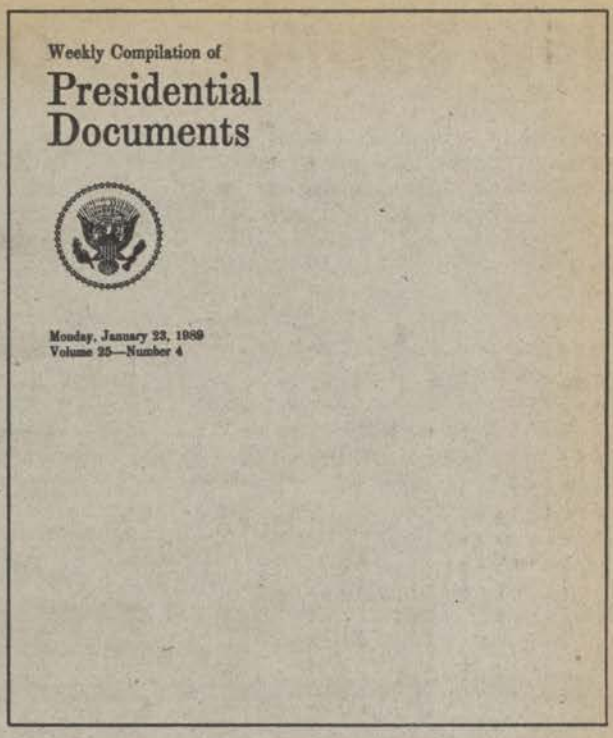

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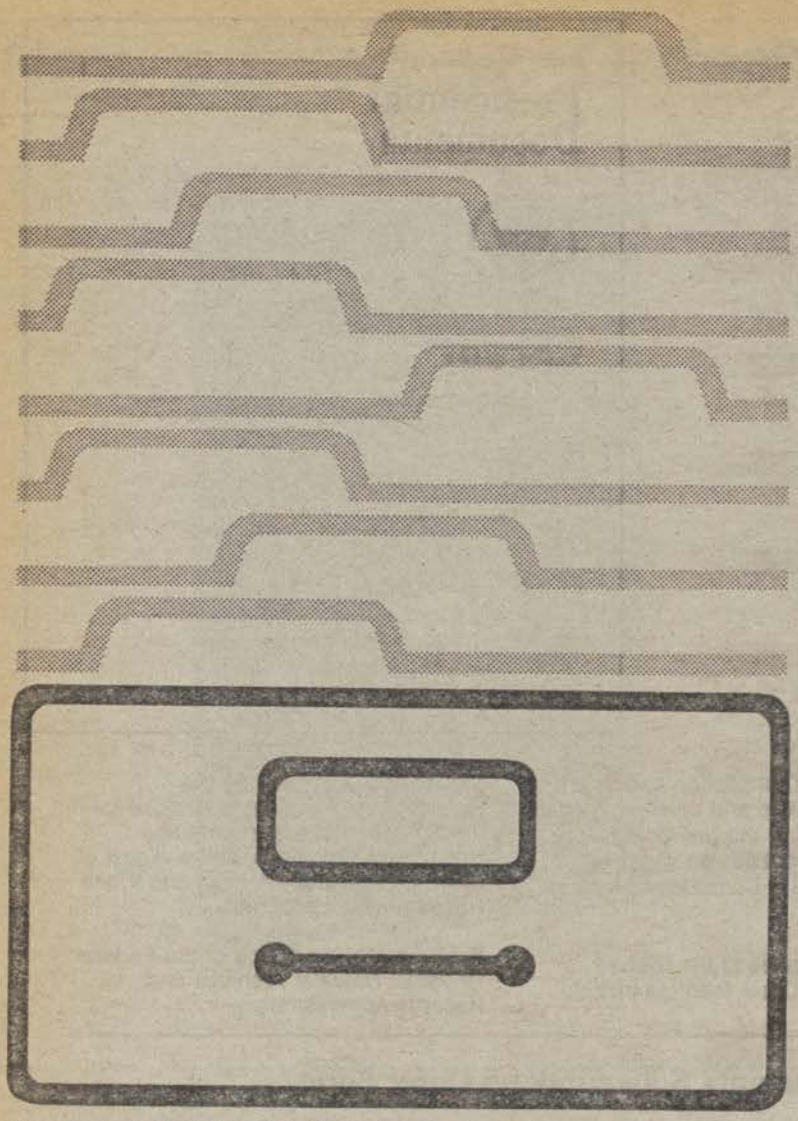

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